January 22, 2024

MegaGen Implant Co., Ltd.
Seo MinGi
45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun
Daegu, 42921
REPUBLIC OF KOREA

Re: K233450
Trade/Device Name: MegaGen Dental Implant Abutment - Scan Healing Abutment; Temporary Abutment; Temporary Cylinder; Comfort Cap; Healing Cap; Healing Cap Screw; Milling Abutment; EZ Post Abutment; Extra EZ Post Abutment; EZ Post Cylinder; ZrGEN Abutment; Multi-unit Abutment; Multi-unit Angled Abutment; AXA Abutment (Straight); AXA Abutment (Angled); Abutment Screw; Cylinder Screw; Crown Screw
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 20, 2023
Received: October 20, 2023

Dear Seo MinGi:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K233450

Device Name

MegaGen Dental Implant Abutment - Scan Healing Abutment; Temporary Abutment; Temporary Cylinder; Comfort Cap; Healing Cap; Healing Cap Screw; Milling Abutment; EZ Post Abutment; Extra EZ Post Abutment; EZ Post Cylinder; ZrGEN Abutment; Multi-unit Abutment; Multi-unit Angled Abutment; AXA Abutment (Straight); AXA Abutment (Angled); Abutment Screw; Cylinder Screw; Crown Screw

Indications for Use *(Describe)*

MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function.

All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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General Summary of Submission

510(k) Summary for K233450

Date: January 22, 2024

1. Applicant / Submitter

MegaGen Implant Co., Ltd.
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Daegu, Republic of Korea
Tel: + 82-53-222-2828

2. Submission Correspondent

MinGi Seo
MegaGen Implant Co., Ltd.
45, Secheon-ro, 7-gil, Dasa-eup, Dalseong-gun,
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3. Device

- Trade Name: MegaGen Dental Implant Abutment - Scan Healing Abutment; Temporary Abutment; Temporary Cylinder; Comfort Cap; Healing Cap; Healing Cap Screw; Milling Abutment; EZ Post Abutment; Extra EZ Post Abutment; EZ Post Cylinder; ZrGEN Abutment; Multi-unit Abutment; Multi-unit Angled Abutment; AXA Abutment (Straight); AXA Abutment (Angled); Abutment Screw; Cylinder Screw; Crown Screw
- Common Name: Endosseous Dental Implant Abutment
- Classification Name: Endosseous dental implant abutment
- Classification Product Code: NHA
- Classification regulation: Class II, 21 CFR 872.3630

4. Predicate Device

- **Primary Predicate Device:**
  K110955 AnyRidge Internal Implant System

- **Reference Devices:**
  K122231 XPEED AnyRidge Internal Implant System
  K123988 AnyOne Internal Implant System
  K182448 BLUEDIAMOND Implant System
  K203808 Multi-unit Abutment System
  K210826 Healing Abutment, Cover Screw
  K211812 BLUDEDIAMOND IMPLANT, Abutment Screw
  K220562 TiGEN, ZrGEN, Scan Healing Abutment

K103280 BHdental Implant System
K133377 NobelProcera Angulated Screw Channel Abutment Replace
K231967 ARi ExCon Implant System

5. Description

- **Scan Healing Abutment**

The Scan Healing Abutment is intended for use as an accessory to endosseous dental implants during endosseous and gingival healing to prepare gingival tissue for acceptance of a final abutment and restoration. It is used for non-submerged type surgery or for two-stage surgery. It is made of Ti-6Al-4V-ELI, and offered in machined and anodizing surface. It is supplied using gamma irradiation during manufacturing process. It is single use devices.

The dimensions of Scan Healing Abutment are follows:

Device	Component
Scan Healing Abutment	**XPEED AnyRidge Internal Implant System** Ø 4.7, 5.7 x 6.9, 7.9, 9.9, 11.9mm

The Scan Healing Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K110955 K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4

- **Temporary Abutment**

The Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration and connected to the Fixture with Abutment Screw. It has knurled surface on the top part, which allows for better retention of resin or wax. It is not customizable but used as it is. The Temporary Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Temporary Abutment are follows:

Device	Component
Temporary Abutment	**XPEED AnyRidge Internal Implant System** Ø 4.2, 4.7, 5.7, 6.7 x 6.9, 7.9, 9.9, 11.9 mm **BLUEDIAMOND IMPLANT System** Ø 4.2, 4.7, 5.7, 6.7 x 12.35, 13.85 mm

The Temporary Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K110955 K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448 K211812	Internal Octa	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5

[Note] There is the modification of the Implant System Name for FDA cleared AnyRidge Octa 1 Implant System to BLUEDIAMOND IMPLANT System with K182448. According to below FDA Guidance*, MEGAGEN manages it as a 510(k) VARIANCE REQIEST FORM for changes.

*Deciding When to Submit a 510(k) for a Change to an Existing Device / Guidance for Industry and Food and Drug Administration Staff / Document issued on October 25, 2017.

- **Temporary Cylinder**

The Temporary Cylinder is used in conjunction with Multi-unit Abutment, Multi-unit Angled Abutment or AXA Abutment to provide support for provisional restoration and used for fabricating the single and multi-unit prosthesis. It is connected to the Abutment with Cylinder Screw. It has knurled surface on the top part (Post Cylinder), which allows for better retention of resin or wax. This component is not customizable but used as it is.

The dimensions of Temporary Cylinder are follows:

Device	Component
Temporary Cylinder	**Common** Ø 4.8, 4.9, 5.7 x 12mm

- **Comfort Cap**

Comfort Cap is used for protecting a Solid Abutment after taking impression, and minimizing irritation to tongue and oral mucosa. It easily makes a temporary crown by resin build up.

The dimensions of Comfort Cap are follows:

Device	Component
Comfort Cap	**Common** Ø 5.0 x 5.4mm

- **Healing Cap**

The Healing Cap is intended to be used during intra-oral soft tissue healing to protect the Multi-unit Abutments and Multi-unit Angled Abutments or AXA Abutment (Straight, Angled) and prepare the soft tissue for the prosthetic procedure (temporary and final restoration). It is a two-piece type, connected to the abutment with Cylinder Screw. The Healing Cap is a temporary component used for soft tissue healing.

The dimensions of Healing Cap are follows:

Device	Component
Healing Cap	**Common** Ø 6.8 x 4.2, 5.5 mm Ø 4.9 x 5.5 mm Ø 5.0, 5.5, 6.0, 6.1, 6.5 x 6.0, 8.0 mm

- **Healing Cap Screw**

Healing Cap Screw is used for connecting AXA Abutment (Straight) or AXA Abutment (Angled) to Healing Cap. It is made of Ti-6Al-4V-ELI and offered in machined surface. The Healing Cap Body Screw is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Healing Cap are follows:

Device	Component
Healing Cap Screw	**Common** Ø 2.5 x 3.3 mm

- **Milling Abutment**

The Milling Abutment is used in conjunction with fixture to provide support for cement and screw retained type final prosthesis and used for establishing an adequate safety margin from occlusal line by hand milling of the post part. It is connected to the Fixture with Abutment Screw. The Milling Abutment can be modified in post height only (The minimum post height is 4mm above the abutment collar/gingival height). The Milling abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Milling Abutment are follows:

Device	Component
Milling Abutment	**XPEED AnyRidge Internal Implant System** Ø 4.0 x 22.4mm

The Milling Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K110955 K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4

- **EZ Post Abutment/Extra EZ Post Abutment**

The EZ Post Abutment is used in conjunction with fixture to provide support for cement and screw retained type final prosthesis. It is connected to the Fixture with Abutment Screw. It is made of Ti-6AI-4V-ELI, and offered in machined, anodizing blue, gold, brown and green. The EZ Post abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of EZ Post Abutment are follows:

Device	Component
EZ Post Abutment /Extra EZ Post Abutment	**XPEED AnyRidge Internal Implant System** Ø 5.0 x 12.9mm Post Height: 5.5mm **BLUEDIAMOND IMPLANT System** Ø 4.0, 5.0 x 7.85, 8.85, 9.35, 9.85, 10.35, 10.85, 11.35, 11.85,12.35, 12.85, 13.35, 13.85, 14.85mm Ø 6.0, 7.0 x 9.35, 10.35, 10.85, 11.35, 11.85,12.35, 12.85, 13.35, 13.85, 14.35, 14.85, 15.35, 16.35mm Post Height: 4.0, 7.0 mm

The EZ Post Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K110955 K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
MegaGen Implant Co., Ltd.	BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448 K211812	Internal Octa	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5, 5.6, 6.0, 6.5, 7.0

[Note] There is the modification of the Implant System Name for FDA cleared AnyRidge Octa 1 Implant System to BLUEDIAMOND IMPLANT System with K182448. According to below FDA Guidance*, MEGAGEN manages it as a 510(k) VARIANCE REQIEST FORM for changes.

*Deciding When to Submit a 510(k) for a Change to an Existing Device / Guidance for Industry and Food and Drug Administration Staff / Document issued on October 25, 2017.

- **EZ Post Cylinder**

The EZ Post Cylinder is used in conjunction with Multi-unit Abutment or Multi-unit Angled Abutment or AXA abutment to provide support for provisional restoration and used for fabricating the single and multi-unit prosthesis. It is connected to the Abutment with Cylinder Screw.

The dimensions of EZ Post Cylinder are follows:

Device	Component
EZ Post Cylinder	**Common** Ø 4.8, 4.9, 5.7 x 4.2, 5.5, 5.8, 7.0, 9.0 mm Post Height (Total Length) : 4.2, 5.5, 5.8 7.0, 9.0 mm

- **ZrGEN Abutment**

The titanium base is not milled but will be used as it is. The titanium base will be cemented Zirconia top-half with FDA-cleared Dental cement (Kuraray Noritake Dental - PANAVIATM SA Cement Universal Automix, K183537). The ZrGEN Abutment is intended to be sent to a MegaGen-validated milling center for manufacturing Zirconia top-half and for cementing with Zirconia top-half (IVOCLAR VIVADENT, INC. - IPS E.MAX CAD/IPS E.MAX ZIRCAD, K051705).

The ZrGEN Abutment is a two-piece abutment composed of the stock titanium base cemented together with the zirconia top-half to complete the final finished device. This abutment is to be used only with implants placed straight.

The dimensions of ZrGEN Abutment are follows:

Device	Component
ZrGEN Abutment	**XPEED AnyRidge Internal Implant System** Ø 4.5, 5.0, 5.5, 6.0 x 7.5, 8.6, 9.0, 10.1, 11.0, 11.4, 12.4, 13.4, 14.4 mm **BLUEDIAMOND IMPLANT System** Ø 4.4, 4.5 x 6.45, 7.35, 7.95, 8.85, 9.85, 9.95, 10.35, 10.85, 11.35, 13.35 mm **Common** Ø 4.8 x 5.5, 6.5, 8.5 mm

The allowable ranges of design parameters after CAD/CAM patient-matching are follows:

Zirconia top-half	**Minimum wall thickness (mm)**	0.5
	Maximum angulation (°)	0
	Minimum gingival collar (ø)	8
	Maximum gingival collar (ø)	10
	Minimum Gingival collar height (mm)	2
	Maximum Gingival collar height (mm)	5
	Minimum post height above the abutment collar/gingival height(mm)	7
	Maximum post height above the abutment collar/gingival height(mm)	15

The ZrGEN Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K110955 K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448 K211812	Internal Octa	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5, 5.6, 6.0, 6.5, 7.0

[Note] There is the modification of the Implant System Name for FDA cleared AnyRidge Octa 1 Implant System to BLUEDIAMOND IMPLANT System with K182448. According to below FDA Guidance*, MEGAGEN manages it as a 510(k) VARIANCE REQIEST FORM for changes.

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- **Multi-unit Abutment**

The Multi-unit Abutment is a straight type, the lower part is intended to be placed on the endosseous dental implant and the top part is connected Healing Cap, Impression Coping or Cylinders, such as Temporary Cylinder and CCM Cylinder with the Screw to fabricate temporary or final prosthesis.

The Multi-unit Abutment is a one-piece type and not contained an anti-rotational feature, allowing the abutment to be screwed directly in to the endosseous dental implant by their lower threaded part. The thread part has three types of male screws depending on the fixture system to be connected. The Multi-unit Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Multi-unit Abutment are follows:

Device	Component
Multi-unit Abutment	**XPEED AnyRidge Internal Implant System** Ø 4.8 x 12.75, 13.75 mm **BLUEDIAMOND IMPLANT System** Ø 4.8 x 14.8, 13.8 mm **AnyOne Internal Implant System** Ø 4.8 x 13.84, 14.84 mm

The Multi-unit Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	Internal Hex	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3
	BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448	Internal Octa	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5

[Note] There is the modification of the Implant System Name for FDA cleared AnyRidge Octa 1 Implant System to BLUEDIAMOND IMPLANT System with K182448. According to below FDA Guidance*, MEGAGEN manages it as a 510(k) VARIANCE REQIEST FORM for changes.

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- **Multi-unit Angled Abutment**

The Multi-unit Angled Abutment is an angled type, the lower part is intended to be placed on the endosseous dental implant and the top part is connected Healing Cap, Impression Coping or Cylinders, such as Temporary Cylinder and CCM Cylinder with the Screw to fabricate temporary or final prosthesis.

The Multi-unit Angled Abutment is a two-piece type, contained an anti-rotational feature, and connected to the endosseous dental implant by Multi-unit Abutment Screw. The Multi-unit Angled Abutment is an angled type and available in 17° and 30°. The Multi-unit Angled Abutment is compatible with the prosthetics which are described in this submission. The Multi-unit Angled Abutment is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Multi-unit Abutment are follows:

Device	Component
Multi-unit Angled Abutment	**XPEED AnyRidge Internal Implant System** Ø 4.8 x 7.4, 7.9, 8.4, 8.9 mm **BLUEDIAMOND IMPLANT System** Ø 4.8 x 8.35, 9.35, 9.85, 10.85 mm **AnyOne Internal Implant System** Ø 4.8 x 7.94, 8.94 mm

The Multi-unit Abutment, Multi-unit Angled Abutment is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	Internal Hex	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3
	BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448	Internal Octa	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5

[Note] There is the modification of the Implant System Name for FDA cleared AnyRidge Octa 1 Implant System to BLUEDIAMOND IMPLANT System with K182448. According to below FDA Guidance*, MEGAGEN manages it as a 510(k) VARIANCE REQIEST FORM for changes.

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- **AXA Abutment (Straight)**

The straight type of AXA Abutment, the lower part is intended to be placed on the endosseous dental implant and the top part is connected Healing Cap, Impression Coping or Cylinders, such as Temporary Cylinder and EZ Post Cylinder with the Screw to fabricate temporary or final prosthesis.

The dimensions of AXA Abutment (Straight) are follows:

Device	Component
AXA Abutment (Straight)	**XPEED AnyRidge Internal Implant System** Ø 4.0, 5.0 x 11.05, 12.05, 13.05, 15.05, 17.05, 19.05 mm **BLUEDIAMOND IMPLANT System** Ø 4.0, 5.0 x 12.10, 13.10, 14.10, 16.10, 18.10, 20.10 mm **AnyOne Internal Implant System** Ø 4.0, 5.0 x 12.143, 13.143, 14.143, 16.143, 18.143, 20.143 mm

The AXA Abutment (Straight) is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K110955 K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	Internal Hex	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3
	BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448 K211812	Internal Octa	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5, 5.6, 6.0, 6.5, 7.0

- **AXA Abutment (Angled)**

The angled type of AXA Abutment, the lower part is intended to be placed on the endosseous dental implant and the top part is connected Healing Cap, Impression Coping or Cylinders, such as Temporary Cylinder and EZ Post Cylinder with the Screw to fabricate temporary or final prosthesis. The angled type of AXA Abutment is a two-piece type, contained an anti-rotational feature, and connected to the endosseous dental implant by Abutment Screw. There are two connection types: the internal hex/octa type and the non-hex/non-octa type.

The dimensions of AXA Abutment (Angled) are follows:

Device	Component
AXA Abutment (Angled)	**XPEED AnyRidge Internal Implant System** Ø 4.0, 5.0 x 6.4, 8.4, 10.4 mm **BLUEDIAMOND IMPLANT System** Ø 4.0, 5.0 x 6.85, 8.85, 10.85 mm **AnyOne Internal Implant System** Ø 4.0, 5.0 x 6.64, 8.64, 10.64 mm

The AXA Abutment (Angled) is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K110955 K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	AnyOne Internal Implant System	AnyOne Internal Fixure	K123988	Internal Hex	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3
	BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448 K211812	Internal Octa	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5, 5.6, 6.0, 6.5, 7.0

- **Abutment Screw**

The Abutment Screw is used for connecting abutment for each Implant System. The lower part has male screws depending on the fixture system to be connected. It is made of Ti-6AI-4V-ELI and offered in machined surface. The Abutment Screw is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Abutment Screw are follows:

Device	Component
Abutment Screw	**XPEED AnyRidge Internal Implant System** Ø 2.0 x 8.5, 9.45, 11.45 mm **BLUEDIAMOND IMPLANT System** Ø 2.2 x 9.9, 7.9 mm **AnyOne Internal Implant System** Ø 2.1 x 9.6, 10.6, 12.6 mm

The Abutment Screw is compatible with following MegaGen Implants cleared under:

Manufacturer	Compatible Implant System	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Fixture	K110955 K122231 K123870 K140091	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	AnyOne Internal Implant System	AnyOne Internal Fixture	K123988	Internal Hex	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3
	BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT	K182448 K211812	Internal Octa	3.6, 3.7, 4.0, 4.1, 4.4, 4.8, 5.0, 5.5, 5.6, 6.0, 6.5, 7.0

- **Cylinder Screw**

Cylinder Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment or AXA Abutment to Healing Cap, Temporary cylinder or EZ Post Cylinder or CCM Cylinder. It is made of Ti-6AI-4V-ELI and offered in machined surface. The Cylinder Screw is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Cylinder Screw are follows:

Device	Component
Cylinder Screw	**Common** Ø 2.1 x 4.9 mm

- **Crown Screw**

The Crown Screw is a prosthetic component connected to abutment and intended for use as an aid in prosthetic rehabilitation. It is made of Ti-6AI-4V-ELI and offered in machined surface. The crown Screw is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.

The dimensions of Crown Screw are follows:

Device	Component
Crown Screw	**Common** Ø 2.3, 2.4 x 5.2, 7.0mm Ø 2.1 x 4.65 mm

6. Indications for use

The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.

7. Basis for Substantial Equivalence

The MegaGen Dental Implant Abutment is substantially equivalent to the predicate device in terms of indication for use, technical characteristic and function. They are made of the same material and have similar design. The size range of the subject of the subject device slightly differ from the predicate device however it is very minor not

affecting substantial equivalence.

Based on the comparison charts below and test results provided in this submission, we conclude that the subject device is substantially equivalent to the predicate device.

(1) Scan Healing Abutment

	Subject Device	Predicate device	Reference Device
510(k) No.	-	K110955	K220562
Device Name	**Scan Healing Abutment**	**Healing Abutment**	**Scan Healing Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	Scan Healing Abutment is intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation.
Design			
Diameter (Ø)	4.7, 5.7 mm	4.2, 5.2, 6.2, 7.2, 10.0 mm	4.2, 4.7, 5.7, 6.7 mm
Gingival Height	2.4, 3.4, 5.4, 7.4 mm	3.5, 4.5, 5.5, 6.5, 7.5 mm	2.4, 3.4, 5.4, 7.4 mm
Total Length	6.9 ~ 11.9 mm	8.4 ~ 14.4 mm	6.9 ~ 11.85mm
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6A1-4V ELI(ASTM F136-13)	Ti-6A1-4V ELI(ASTM F136-13)	Ti-6A1-4V ELI(ASTM F136-13)
Surface Treatment	Anodizing	Machined	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Shelf-life	5 years	5 years	5 years
Principle of Operation	The Scan Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping. And it is a scannable that can help with the impression intraoral without removal.	The Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping.	The Scan Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping. And it is a scannable that can help with the impression intraoral without removal.
Compatible Implant System	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device and reference device.

- Indications for Use, Design, Diameter, Gingival Height, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Shelf Life, Principle of Operation

2. Difference

The subject device has the different characteristics for the followings compared to the predicate device.

- Total Length

  The total length of the subject device (11.9 mm) is longer than the reference device and other lengths are within range of the reference device. Since this size difference is very minor it does not cause a matter in substantial equivalence. And the total length includes the connection length of each implant system and therefore does not affect substantial equivalence.

3. Discussion

The Subject device and predicate device have common in Indications for sue, Design, Diameter, Gingival Height, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Shelf Life and Principle of Operation. And the difference is only the total Length. But these do not affect device's substantial equivalence. Also, the subject device is intended for temporary use.

- Based on the information in the submission, it is concluded that the subject device is substantially equivalent to the predicate device.

(2) Temporary Abutment

	Subject Device	Predicate Device	Reference Device1	Reference Device2
510(k) No.	-	K110955	K182448	K203808
Device Name	**Temporary Abutment**	**Temporary Abutment**	**Temporary Abutment**	**Multi-unit Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situation and with the clinical protocols: - Immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
Design				
Diameter (Ø)	3.5,4.0, 4.5, 4.75 mm	4.0, 5.0 mm	4.0, 4.5, 5.0 mm	4.8 mm
Gingival Height	1.8, 2.0, 2.2,2.8, 3.0, 3.2, 3.8, 4.0, 4.2,4.8, 5.0, 5.2 mm	2.0 mm	2.0, 3.0 mm	0.6, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm
Post Height	7.5, 10.0 mm	10 mm	10.0 mm	1.8, 2.2 mm
Total Length	14.4 ~ 19.35 mm	14.4 mm	14.85 ~ 17.35mm	6.2 ~ 12.84mm
Angulation	Straight	Straight	Straight	Straight
Connection Interface	Hex, Non-Hex Octa, Non-Octa	Hex, Non-Hex	Octa, Non-Octa	Hex, Non-Hex
Material	Ti-6A1-4V ELI(ASTM F136-13)	Ti-6A1-4V ELI(ASTM F136-13)	Ti-6A1-4V ELI(ASTM F136-13)	Ti-6A1-4V ELI(ASTM F136-13)
Surface Treatment	Machined, Anodizing	Machined	Machined, Anodizing	Anodizing
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Temporary Abutment is a superstructure which is connected to the Fixtures or Regular Abutment using the Abutment Screw. It is used to provide support for provisional restoration.	The Temporary Cylinder is a superstructure which is connected to the Abutment using the Screw. It is used to provide support for provisional restoration.	The Temporary Abutment is a superstructure which is connected to the Fixtures using the Screw. It is used to provide support for provisional restoration.	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.
Compatible Implant System	XPEED AnyRidge Internal Implant System BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System	BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate and reference devices.

- Indications for Use, Design, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the predicate device and reference device.

- Diameter

Some of diameter (3.5mm) of subject device is smaller than the predicate device and reference device while other diameters are within the range of the predicate and reference devices. The difference in size is very small, so the issue of substantive equivalence does not arise. And the variety of sizes allows for more precise treatment tailored to each patient's condition.

- Gingival Height

Some of the gingival heights of subject device are different from the predicate device. However, the overall dimensions are within the range of Megagen's licensed reference device. Although there is a difference in the period of use, there is no problem substantive equivalence regarding dimensions. And the variety of sizes allows for more precise treatment tailored to each patient's condition.

- Post Height

Some post heights (7.5mm) of the subject device are smaller than the predicate device and reference device while other diameters are within the range of the predicate and reference devices. The difference in size is small, so the issue of substantive equivalence does not arise. And the variety of sizes allows for more precise treatment tailored to each patient's condition.

- Total Length

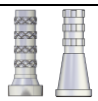
The Total Length of the subject device is longer than the predicate device and the reference device. But the longer total length of the subject device does not cause a matter in substantial equivalence since the subject device is intended for temporary use. And the total length includes the connection length of each implant system and therefore does not affect substantial equivalence.

3. Discussion

The subject device and predicate device, reference device have common in Indication for use, Design, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence. Also, the subject device is intended for temporary use.

- Based on the information based in submission, we conclude that the subject device is substantially equivalent to the predicate device and reference device.

(3) Temporary Cylinder

	Subject Device	Predicate device	Reference Device1	Reference Device2
510(k) No.	-	K110955	K203808	K123988
Device Name	**Temporary Cylinder**	**Temporary Cylinder**	**Temporary Cylinder**	**Temporary Cylinder**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design				
Diameter (Ø)	4.8, 4.9, 5.7 mm	3.8, 4.8, 5.8 mm	4.8 mm	3.87, 4.8, 5.8 mm
Gingival Height	3.0 mm	3.0 mm	3.0 mm	2.8, 3.0 mm
Post Height	8.5 mm	7.0 mm	8.5 mm	7.0, 7,5 mm
Total Length	12.0 mm	10.0 mm	12.0 mm	10.0, 12.35 mm
Angulation	Straight	Straight	Straight	Straight
Connection Interface	Internal Non-Hex	Internal Non-Hex	Internal Octa, Internal Non-Octa	Internal Octa, Non-Octa Internal Hex, Non-Hex
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	CP Ti Grade 4 (ASTM F67-13)
Surface Treatment	Machined	Machined	Machined	Machined
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	Temporary Cylinder is used in conjunction with Multi-unit Abutment to provide support for provisional restoration.	Temporary Cylinder is used in conjunction with Multi-unit Abutment to provide support for provisional restoration.	Temporary Cylinder is used in conjunction with Multi-unit (Angled) Abutment (N type) to provide support for provisional restoration.	Temporary Cylinder is used in conjunction with Octa Abutment and Multi-unit (Angled) Abutment (S type) to provide support for provisional restoration.
Compatible Implant System	XPEED AnyRidge Internal Implant System BLUDIAMOND Implant System	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUDIAMOND Implant System	AnyOne Internal Implant System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device and reference devices.

- Indication for use, Design, Gingival Height, Post Height, Total Length, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Principle of Operation
- Diameter

2. Differences

The subject device has the different characteristic for the followings compared to the predicate device and reference device.

- Diameter

  Some diameters (4.9, 5.7 mm) of the subject device are different from the predicate and reference devices, but they are all within the range of the predicate device, and other diameters (4.8 mm) are the same as the predicate device. The difference in size is very small, so the issue of substantive equivalence does not arise. And the variety of sizes allows for more precise treatment tailored to each patient's condition.

3. Discussion

The subject device and reference devices have common in all the items except the Diameter. The Diameter differences are explained not affecting on the substantial equivalence.

- Based on the information based in submission, we conclude that the subject device is substantially equivalent to the reference devices.

(4) Comfort Cap

	Subject Device	Predicate device	Reference Device
510(k) No.		K110955	K123988
Device Name	**Comfort Cap**	**Comfort Cap**	**Comfort Cap**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The AnyOne™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø)	5.5 mm	4.0, 5.0, 6.0, 7.0 mm	4.0, 4.5, 5.5, 6.5 mm
Total Length	5.4 mm	5.4 ~ 8.4 mm	5.4 ~ 8.6 mm
Material	POM	POM	POM
Single Use	Yes	Yes	Yes
Sterilization	Non-Sterile	Non-Sterile	Non-Sterile
Principle of Operation	The Comfort Cap is used for protecting a Solid Abutment after taking impression, and minimizing irritation to tongue and oral mucosa. It easily makes a temporary crown by resin build up.	The Comfort Cap is used for protecting a Solid Abutment after taking impression, and minimizing irritation to tongue and oral mucosa. It easily makes a temporary crown by resin build up.	The Comfort Cap is used for protecting a Solid Abutment after taking impression, and minimizing irritation to tongue and oral mucosa. It easily makes a temporary crown by resin build up.
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System	AnyOne Internal Implant System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device and reference device.

- Indications for Use, Design, Diameter, Total length, Material, Single Use, Sterilization, Principle Operation

2. Differences

There are no differences with the predicate device and reference device.

3. Discussion

The subject device and reference device have common in Indications for Use, Design, Diameter, Total length, Material, Single Use, Sterilization, and Principle Operation.

(5) Healing Cap

	Subject Device	Predicate device		Reference Device
510(k) No.	-	K110955		K203808
Device Name	**Healing Cap**	**Healing Cap**	**Comfort Cap**	**Healing Cap**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.		The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
Design				
Diameter (Ø)	4.9, 5.0, 5.5, 6.0, 6.1, 6.5, 6.8 mm	4.0, 6.0 mm	4.0, 5.0, 6.0, 7.0 mm	4.9, 6.8 mm
Total Length	4.2 ~ 8.0 mm	3.70 ~ 3.75mm	5.4 ~ 8.4 mm	4.2 mm
Connection Interface	Two-piece Healing Cap (with titanium alloy screw)	Two-piece Healing Cap (with titanium alloy screw)	One-piece	Two-piece Healing Cap (with titanium alloy screw)
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	POM	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined, Anodizing	Machined	Non-Sterile	Machined
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Healing Cap is intended to be used during intra-oral soft tissue healing to protect the Multi-unit Abutments and Multi-unit Angled Abutments or AXA Abutment (Straight, Angled) and prepare the soft tissue for the prosthetic procedure (temporary and final restoration). It is a two-piece type, connected to the abutment with Cylinder Screw. The Healing Cap is a temporary component used for soft tissue healing.	Healing Cap is used for protecting Octa Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing.	The Comfort Cap is used for protecting a Solid Abutment after taking impression, and minimizing irritation to tongue and oral mucosa. It easily makes a temporary crown by resin build up.	Healing Cap is used for protecting Multi-unit Abutment or Multi-unit Angled Abutment and minimizing irritation to tongue and oral mucosa during period of gingival healing.
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device and reference device.

- Indication for use, Design, Connection Interface, Material, Single Use, Sterilization, Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the predicate and reference devices.

- Diameter
  Some of diameters (5.0, 5.5, 6.1, 6.5 mm) of subject device are slightly different with the predicate device and reference device while other diameters are within the range of the predicate device and reference device. The difference in size is very small, so the issue of substantive equivalence does not arise. And the variety of sizes allows for more precise treatment tailored to each patient's condition.
- Total Length
  The total length of the subject device is different from predicate device but is within the range of the predicate device. So the issue of substantive equivalence does not arise. And the variety of sizes allows for more precise treatment tailored to each patient's condition.
- Surface Treatment
  The subject device is treated with machined and anodizing while the predicate device is treated with machined, but anodizing, a surface treatment method, is the same as the MegaGen's cleared reference device in other comparison tables.

3. Discussion

- The subject device and predicate device, reference device have common in Indication for use, Design, Connection Interface, Material, Single Use, Sterilization and Principle of Operation. The dimension is slightly different with the predicate device and the reference device, but it does not cause a matter in substantial equivalence since the size difference is very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Also, the subject device is intended for temporary use.

- Based on the information based in submission, we conclude that the subject device is substantially equivalent to the reference devices.

(6) Healing Cap Screw

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.	-	K123988	K203808
Device Name	**Healing Cap Screw**	**Flat Cylinder Screw**	**Cylinder Screw**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyOne™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
Design			
Diameter (Ø)	2.5 mm	2.1 mm	2.0 mm
Total Length	3.30 mm	5.9 mm	3.4 mm
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Machined
Single Use	Yes	Machined	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	Healing Cap Screw is used for connecting AXA Abutment (Straight) or AXA Abutment (Angled) to Healing Cap. It is made of Ti-6Al-4V-ELI and offered in machined surface. The Healing Cap Body Screw is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.	Flat Cylinder Screw is used for connecting Abutment or Healing cap or Cylinder.	Cylinder Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to Healing Cap, Temporary cylinder or CCM Cylinder.
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Material, Surface Treatment, Single Use, Sterilization, Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the predicate and reference devices.

- Diameter

  The Diameter of subject device is slightly different with the Reference devices. But, the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

- Total Length

  The Total Length of subject device is slightly different with the Reference device2. But, the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

3. Discussion

The subject device and reference devices have common in Indication for use, Design, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation. The Diameter and Total Length are slightly different with reference devices, but it does not cause a matter in substantial equivalence since the size differences are very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Also, the subject device is intended for temporary use.

- Based on the information based in submission, we conclude that the subject device is substantially equivalent to the reference devices.

(7) Milling Abutment

	Subject Device	Predicate Device	Reference Device
510(k) No.	-	K110955	K182448
Device Name	**Milling Abutment**	**Milling Abutment**	**Milling Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The Xpeed AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situation and with the clinical protocols: - Immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Design			
Diameter (Ø)	4.0 mm	4.0, 5.0, 6.0, 7.0mm	6.0, 8.0 mm
Gingival Height	0.8 mm	2.8 mm	0.8, 1.8, 2.8, 3.8, 4.8 mm
Post Height	19.0 mm	9.2 mm	9.0 mm
Total Length	22.4 mm	12.35 mm	18.35 mm
Angulation	Straight	Straight	Straight
Connection Interface	Hex, Non-Hex	Hex, Non-Hex	Octa, Non-Octa
Material	Ti-6A1-4V ELI(ASTM F136-13)	Ti-6A1-4V ELI(ASTM F136-13)	Ti-6A1-4V ELI(ASTM F136-13)
Surface Treatment	Anodizing	Anodizing	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.
Compatible Implant System	XPEED AnyRidge Internal Implant System	XPEED AnyRidge Internal Implant System	BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device and reference device.

- Indication for use, Design, Diameter, Gingival Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the predicate and reference devices.

- Post Height, Total Length

The Total length and Post height of the subject device is longer than the predicate device and reference device. But it does not matter in substantial equivalence since the milling abutment is designed so that the height of the post part can be modified by hand milling. Also, In order to evaluate the stability and performance due to differences in the submitted devices, we selected subjected AXA Abutment (Angled type) as the worst case representative device and conducted a fatigue test. Test results confirmed that there was no essential difference in product performance and stability.

3. Discussion

The subject device and predicate device and reference device have common in Indication for use, Design, Diameter, Gingival Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

Also, In order to evaluate the stability and performance due to differences in the submitted devices, we selected the worst model and conducted a fatigue test. Test results confirmed that there was no difference in Substantial equivalence.

- Based on the information based in submission, we conclude that the subject device is substantially equivalent to the predicate device and reference device.

(8) EZ Post Abutment

	Subject Device	Predicate Device	Reference Device
510(k) No.	-	K110955	K182448
Device Name	**EZ Post Abutment**	**EZ Post Abutment**	**EZ Post Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The Xpeed AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situation and with the clinical protocols: - Immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Design			
Diameter (Ø)	4.0, 5.0, 6.0, 7.0mm	4.0, 5.0, 6.0, 7.0mm	4.0, 5.0, 6.0, 7.0mm
Gingival Height	0.8, 1.8, 2.8, 3.8, 4.8, 5.0mm	1.8, 2.8, 3.8, 4.8mm	0.8, 1.8, 2.8, 3.8, 4.8 mm
Post Height	4.0, 5.5, 7mm	5.5, 7mm	4.0, 5.5, 7mm
Total Length	6.15 ~ 13.15 mm	7.85 ~ 16.35 mm	7.85 ~ 14.85 mm
Angulation	Straight	Straight	Straight
Connection Interface	Hex, Non-hex Octa, Non-Octa	Hex, Non-hex	Octa, Non-Octa
Material	Ti-6A1-4V ELI(ASTM F136-13)	Ti-6A1-4V ELI(ASTM F136-13	Ti-6A1-4V ELI(ASTM F136-13)
Surface Treatment	Anodizing	Anodizing	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.
Compatible Implant System	XPEED AnyRidge Internal Implant System BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System	BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the predicate device and reference device.

- Indication for use, Design, Diameter, Post height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

2. Differences

The subject device has the different characteristic for the followings compared to the predicate device and reference device.

- Gingival Height

Some of the Gingival Height (5mm) is longer than the predicate device and reference device while other Gingival Heights are same with the predicate device and reference device. The difference in size is very small, so the issue of substantive equivalence does not arise. Also, In order to evaluate the stability and performance due to differences in the submitted devices, we selected subjected AXA Abutment (Angled type) as the worst case representative device and conducted a fatigue test. Test results confirmed that there was no essential difference in product performance and stability.

- Total Length

The Total Length of the subject device is slightly different with the predicate device and reference device. But, the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

3. Discussion

The subject device and reference device have common in Indication for use, Design, Diameter, Post height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

Also, In order to evaluate the stability and performance due to differences in the submitted devices, we selected the worst model and conducted a fatigue test. Test results confirmed that there was no difference in Substantial equivalence.

- Based on the information based in submission, we conclude that the subject device is substantially equivalent to the reference device.

(9) EZ Post Cylinder

	Subject Device	Reference Device 1	Reference Device 2
510(k) No.		K182448	K203554
Device Name	**EZ Post Cylinder**	**EZ Post Cylinder**	**EZ Post Cylinder**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situation and with the clinical protocols: - Immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
Design			
Diameter (Ø)	4.8, 4.9, 5.7 mm	4.0, 5.0, 6.0 mm	5.0 mm
Total Length	4.2 ~ 9.0 mm	5.5 ~ 7.0 mm	8.5 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Non-Hex	Octa, Non-Octa	Hex, Non-Hex
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6A1-4V ELI(ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined, Anodizing	Anodizing	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	EZ Post Cylinder is used in conjunction with Multi-unit Abutment or AXA Abutment to provide support for provisional restoration.	EZ Post Cylinder is used in conjunction with Octa Abutment to provide support for cement and screw type final prosthesis. EZ Post Cylinder and Octa Abutment are connected by combining the female screw on the top of the Octa Abutment and Cylinder Screw.	The EZ Post Cylinder is used in conjunction with Regular Abutment to provide support for cement and screw type final prosthesis. It is connected to the Abutment using Abutment Screw.
Compatible Implant System	XPEED AnyRidge Internal Implant System BLUDIAMOND IMPLANT System AnyOne Internal Implant System	BLUDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System BLUDIAMOND IMPLANT System AnyOne Internal Implant System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference device.

- Indication for use, Design, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference device.

- Diameter

  All of diameters of the subject device are different with the reference devices but the different diameters are within range of the reference device 1. Also, the difference in size is very small, so the issue of substantive equivalence does not arise. And the variety of sizes allows for more precise treatment tailored to each patient's condition.

- Total Length

  The total length of the subject device (9.0mm) is slightly longer than the total length of reference device (8.5mm). For the longest length (9.0 mm), fatigue testing was performed by connecting it with an AXA abutment (Angled type). Test results confirmed that there was no substantial difference in product performance and stability.

3. Discussion

The subject device and reference device have common in Indication for use, Design, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation. Also, the proposed product is a straight type abutment so the fatigue test was performed as a representative of the worst case model with angle.

- Based on the information based in submission, we conclude that the subject device is substantially equivalent to the reference

devices.

(10) ZrGEN Abutment

	Subject Device	Predicate device	Reference Device 1	Reference Device 2
510(k) No.		K110955	K123988	K220562
Device Name	**ZrGEN Abutment**	**EZ Post Abutment**	**ZrGEN Abutment**	**ZrGEN Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The Xpeed AnyRidge Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The AnyOne™ Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The TiGEN Abutment, ZrGEN Abutment and Scan Healing Abutment are intended for use on endosseous dental implants in the edentulous or partially edentulous maxilla or mandible, as an aid in prosthetic rehabilitation. For TiGEN Abutment and ZrGEN Abutment, all digitally designed abutments for use with TiGEN Abutment and ZrGEN Abutment are intended to be sent to a MegaGen-validated milling center for manufacture.
Titanium base component representative image				
Diameter (Ø) of the titanium base component	4.0, 4.5, 4.8, 5.0, 5.5, 6.0 mm	4.0, 5.0, 6.0, 7.0mm	4.0, 4.4, 5.0, 5.5, 6.5mm	3.9, 4.0, 4.3, 4.5, 5.0, 5.5, 6.0 mm
Gingival Height of the titanium base component	0.6, 1.5, 2.3, 3.0, 4.0 mm	1.8, 2.8, 3.8, 4.8 mm	0.6, 1.5, 3.0, 4.0 mm	0.6, 1.5, 3.0, 4.0 mm
Post Height of the titanium base component	4.5, 5.5, 6.0, 6.2,6.5, 8.0, 8.5 mm	5.5, 7 mm	4.5, 6.0, 8.0 mm	4.5, 6.0, 8.0 mm
Total Length	4.5 ~ 14.4 mm	7.85 ~ 16.35 mm	5.8 ~ 8.9 mm	7.5 ~10.10 mm
Angulation	Ti base (0°), Zirconia top half (0°)	Straight	Ti base (0°), Zirconia top half (0°)	Ti base (0°), Zirconia top half (0°)
Connection Interface	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection
Material	Ti-6A1-4V ELI(ASTM F136-13) *Zirconia (K051705)	Ti-6A1-4V ELI(ASTM F136-13)	Ti-6A1-4V ELI(ASTM F136-13) *Zirconia (K051705)	Ti-6A1-4V ELI(ASTM F136-13) *Zirconia (K051705)
Surface Treatment	Machined	Anodizing	Machined	Machined
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-Sterile	Non-Sterile	Non-Sterile	Gamma sterilization
Principle of Operation	The ZrGEN Abutment is used to provide support for customized prosthetic restorations such as copings and crowns using FDA-clear Zirconia block. The ZrGEN Abutment itself is not to be machined but used as it is. The Zirconia top-half of ZrGEN Abutments are intended to be sent to a MegaGen-validated milling center for manufacture and must be designed with the	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	The ZrGEN Abutment is used to provide support for customized prosthetic restorations such as copings and crowns using FDA-clear Zirconia block. The ZrGEN Abutment itself is not to be machined but used as it is. The Zirconia top-half of ZrGEN Abutments are intended to be sent to a MegaGen-validated milling	The ZrGEN Abutment is used to provide support for customized prosthetic restorations such as copings and crowns using FDA-clear Zirconia block. The ZrGEN Abutment itself is not to be machined but used as it is. The Zirconia top-half of ZrGEN Abutments are intended to be sent to a MegaGen-validated milling

	allowable range of design parameters provided by MegaGen.		center for manufacture and must be designed with the allowable range of design parameters provided by MegaGen.	center for manufacture and must be designed with the allowable range of design parameters provided by MegaGen.
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System	AnyOne Internal Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Diameter, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Gingival Height

Some Gingival Heights (0.6, 1.5, 3.0, 4.0 mm) of the subject device are same with the reference devices and other gingival height (2.3 mm) of the subject device is different from the predicate device and reference devices. But the gingival height of the subject device is within range of the reference devices.

- Post Height

Some Post Heights (4.5, 5.5, 6.0, 6.2, 8.0 mm) of the subject device are same with the predicate device, reference devices and other post heights (6.5, 8.5 mm) of the subject device are different from the predicate device and reference devices. But the post height (6.5 mm) is within range of the reference devices. The post height (8.5 mm) of the subject device is slightly longer than the post height of reference device. It does not cause a matter in substantial equivalence since this size difference is very minor, and the variety of the size can be possible to operate more precise treatment to meet each patient's condition.

- Total Length

The total length (4.5 mm) of the subject device is smaller than the reference devices and the total length (14.4 mm) of the subject device is longer then the reference devices. But the smaller total length (4.5mm) is not a worst case of performance testing and the total length includes the connection length of each implant system and therefore does not affect substantial equivalence.

Also, In order to evaluate the stability and performance due to differences in the submitted devices, we selected subjected AXA Abutment (Angled type) as the worst case representative device and conducted a fatigue test. Test results confirmed that there was no essential difference in product performance and stability.

3. Discussion

The subject device and reference devices have common in Indication for use, Design, Diameter, Connection Interface, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation.

Also, the proposed product is a straight type abutment so the fatigue test was performed as a representative of the worst case model with angle.

- Based on the information in the submission, it is concluded that the subject device is substantially equivalent to the predicate device.

(11) Multi-unit Abutment

	Subject Device	Reference Device	
510(k) No.		K182448	K203808
Device Name	**Multi-unit Abutment**	**Multi-unit Abutment**	**Multi-unit Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
Design			
Diameter (Ø)	4.8 mm	4.8 mm	4.8 mm
Gingival Height	5.24, 5.3, 6.24, 6.3 mm	1.3, 2.3, 3.3, 4.3 mm	0.6, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm
Post Height	2.2 mm	2.2 mm	1.8, 2.2 mm
Total Length	12.75 ~ 13.75 mm	9.8 ~ 12.8 mm	6.2 ~ 12.84 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Hex, Internal Non-Hex, Internal Conical Connection	Internal Conical Connection	Internal Hex, Internal Non-Hex, Internal Conical Connection
Material	Ti-6Al-4V ELI(ASTM F136-13)	Ti-6Al-4V ELI(ASTM F136-13)	Ti-6Al-4V ELI(ASTM F136-13)
Surface Treatment	Anodizing	Anodizing, Machined	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Restoration Type	Single & Multi	Single & Multi	Single & Multi
Principle of Operation	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Diameter, Post Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Restoration type, Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Gingival Height, Total Length

All of the differences (Gingival Height and Total Length) are longer than the reference devices. But the total length includes the connection length of each implant system and therefore does not affect substantial equivalence. The variety of the size can be possible to operate more precise treatment to meet each patient's condition. In order to evaluate the stability and performance due to differences in the submitted devices, we selected subjected AXA Abutment (Angled type) as the worst case representative device and conducted a fatigue test. Test results confirmed that there was no essential difference in product performance and

stability.

3. Discussion

The subject device and reference devices have common in Indication for use, Design, Diameter, Post Height, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Restoration type and Principle of Operation.

Also, In order to evaluate the stability and performance due to differences in the submitted devices, we selected the worst model with angle and conducted a fatigue test. Test results confirmed that there was no difference in Substantial equivalence.

- Based on the information in the submission, it is concluded that the subject device is substantially equivalent to the predicate device.

(12) Multi-unit Angled Abutment

	Subject Device	Reference Device	
510(k) No.		K182448	K203808
Device Name	**Multi-unit Angled Abutment**	**Multi-unit Angled Abutment**	**Multi-unit Angled Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
Design			
Diameter (Ø)	4.8 mm	4.8 mm	4.8, 5.0 mm
Gingival Height	5.24, 5.3, 6.24, 6.3 mm	2.3, 3.3, 4.3 mm	1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5 mm
Post Height	2.2 mm	2.2 mm	2.2, 3.9 mm
Total Length	7.4, ~ 10.85 mm	5.35 ~ 8.85mm	3.4~8.85 mm
Angulation	17°, 30°	17°, 30°	17°, 29°, 30°
Connection Interface	Internal Hex, Internal Non-Hex, Internal Octa, Internal Non-Octa	Internal Octa, Internal Non-Octa	Internal Hex, Internal Non-Hex, Internal Octa, Internal Non-Octa
Material	Ti-6Al-4V ELI(ASTM F136-13)	Ti-6Al-4V ELI(ASTM F136-13)	Ti-6Al-4V ELI(ASTM F136-13)
Surface Treatment	Anodizing	Machined	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Restoration Type	Single & Multi	Single & Multi	Single & Multi
Principle of Operation	This product is a pre-manufactured prosthetic component connected to the endosseous dental implant using the screw and is intended for use as an aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component connected to the endosseous dental implant using the screw and is intended for use as an aid in prosthetic rehabilitation.
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System AnyOne internal Implant System BLUEDIAMOND IMPLANT System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Diameter, Post Height, Angulation, Connection Interface, Material, Single Use, Sterilization, Restoration type, Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Gingival Height, Total Length

All of the differences (Gingival Height and Total Length) are longer than the reference devices. But the total length includes the connection length of each implant system and therefore does not affect substantial equivalence. The variety of the size can be possible to operate more precise treatment to meet each patient's condition. In order to evaluate the stability and performance due to differences in the submitted devices, we selected subjected AXA Abutment (Angled type) as the worst case representative device and conducted a fatigue test. Test results confirmed that there was no essential difference in product performance and stability.

3. Discussion

The subject Multi-unit Angled abutment and the reference device have common in Indication for use, Design, Diameter, Post Height,

Angulation, Connection Interface, Material, Single Use, Sterilization, Restoration type and Principle of Operation. The differences are explained not affecting on the substantial equivalence.
Also, the fatigue test was performed on the subjected AXA Abutment (Angled) as the representative model for the worst case with an angle to confirm the substantial equivalence. The test result supports that the subject device is substantially equivalent to the predicate, reference device and the difference it not affecting the substantial equivalence.

- Based on the information in the submission, it is concluded that the subject device is substantially equivalent to the predicate device.

(13) AXA Abutment (Straight)

	Subject Device	Reference Device	
510(k) No.		K182448	K203808
Device Name	**AXA Abutment (Straight)**	**Multi-unit Abutment**	**Multi-unit Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
Design			
Diameter (Ø)	4.0, 5.0 mm	4.8 mm	4.8 mm
Gingival Height	1.8, 2.8, 3.8, 5.8, 7.8 mm	1.3, 2.3, 3.3, 4.3 mm	0.6, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5 mm
Post Height	4.0, 6.0 mm	2.2 mm	1.8, 2.2 mm
Total Length	11.05 ~ 20.1 mm	9.8 ~ 12.8 mm	6.2 ~ 12.84 mm
Angulation	Straight	Straight	Straight
Connection Interface	Internal Hex, Internal Non-Hex, Internal Conical Connection	Internal Conical Connection	Internal Hex, Internal Non-Hex, Internal Conical Connection
Material	Ti-6Al-4V ELI(ASTM F136-13)	Ti-6Al-4V ELI(ASTM F136-13)	Ti-6Al-4V ELI(ASTM F136-13)
Surface Treatment	Anodizing, Machined	Anodizing, Machined	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Restoration Type	Single & Multi	Single & Multi	Single & Multi
Principle of Operation	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System	BLUEDIAMOND IMPLANT System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUEDIAMOND IMPLANT System
Substantial Equivalence Discussion			

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Restoration type, Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Diameter

The diameter (4.0 mm) of the subject device is smaller than the reference devices and other diameter (5.0 mm) is bigger than the reference devices. But, the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

- Gingival Height, Post Height, Total Length

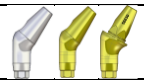
  All of the differences (Gingival, Post Height, and Total Length) are longer than the reference devices. But the total length includes the connection length of each implant system and therefore does not affect substantial equivalence. The variety of the size can be possible to operate more precise treatment to meet each patient's condition. In order to evaluate the stability and performance due to differences in the submitted devices, we selected subjected AXA Abutment (Angled type) as the worst case representative device and conducted a fatigue test. Test results confirmed that there was no essential difference in product performance and stability.

3. Discussion

The subject device and reference devices have common in Indication for use, Design, Angulation, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Restoration type and Principle of Operation. The differences are explained not affecting on the substantial equivalence. Also, the proposed product is a straight type abutment so the fatigue test was performed as a representative of the worst case model with angle.

- Based on the information in the submission, it is concluded that the subject device is substantially equivalent to the predicate device.

(14) AXA Abutment (Angled)

	Subject Device	Reference Device	
510(k) No.		K182448	K203808
Device Name	**AXA Abutment(Angled)**	**Multi-unit Angled Abutment**	**Multi-unit Angled Abutment**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.
Design			
Diameter (Ø)	4.0, 5.0 mm	4.8 mm	4.8, 5.0 mm
Gingival Height	3.8, 5.8, 7.8 mm	2.3, 3.3, 4.3 mm	1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5 mm
Post Height	2.0, 4.0, 6.0 mm	2.2 mm	2.2, 3.9 mm
Total Length	6.4 ~ 10.85 mm	5.35 ~ 8.85mm	3.4 ~ 8.85 mm
Angulation	20°, 30°	17°, 30°	17°, 29°, 30°
Connection Interface	Internal Hex, Internal Non-Hex, Internal Octa, Internal Non-Octa	Internal Octa, Internal Non-Octa	Internal Hex, Internal Non-Hex, Internal Octa, Internal Non-Octa
Material	Ti-6Al-4V ELI(ASTM F136-13)	Ti-6Al-4V ELI(ASTM F136-13)	Ti-6Al-4V ELI(ASTM F136-13)
Surface Treatment	Anodizing, Machined	Machined	Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Restoration Type	Single & Multi	Single & Multi	Single & Multi
Principle of Operation	This product is a pre-manufactured prosthetic component connected to the endosseous dental implant using the screw and is intended for use as an aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component directly or indirectly connected to the endosseous dental implant using its threaded part or screw for aid in prosthetic rehabilitation.	This product is a pre-manufactured prosthetic component connected to the endosseous dental implant using the screw and is intended for use as an aid in prosthetic rehabilitation.
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUDIAMOND Implant System	BLUDIAMOND Implant System	Xpeed AnyRidge Internal Implant System AnyOne Internal Implant System BLUDIAMOND Implant System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Connection Interface, Material, Surface Treatment, Single Use, Sterilization, Restoration type, Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Diameter

  The diameter (4.0 mm) of the subject device is smaller than the reference devices and other diameter (5.0 mm) is bigger than the reference devices. But, the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Therefore, it does not cause a matter in substantial equivalence.

- Gingival Height, Post Height, Total Length,

  The difference between the subject devices is that the total length, Post Height (6.0mm) and Gingival Height (5.7, 7.8 mm) are longer than the reference devices. In order to evaluate the stability and performance due to differences in the submitted devices,

the fatigue test was performed on the subject device to confirm the substantial equivalence. Also, the fatigue test was performed on the subjected AXA Abutment (Angled) as the representative model for the worst case with an angle to confirm the substantial equivalence. The test result supports that the subject device is substantially equivalent to the reference devices and the difference it not affecting the substantial equivalence.

- Angulation

The angles of the subject device are 20° and 30°, 30° angle is the same as the reference device. 20° angle is somewhat different from the reference device, but is within the range of the reference device, so no substantial equivalence issues arise.

3. Discussion

The subject device and reference devices have common in Indication for use, Design, Connection Interface, Material, Single Use, Sterilization, Restoration type and Principle of Operation. The differences are explained not affecting on the substantial equivalence. Also, the fatigue test was performed on the subjected AXA Abutment (Angled) as the representative model for the worst case with an angle to confirm the substantial equivalence. The test result supports that the subject device is substantially equivalent to the reference devices and the difference it not affecting the substantial equivalence.

- Based on the information in the submission, it is concluded that the subject device is substantially equivalent to the predicate device.

(15) Abutment Screw

	Subject Device	Reference Device	
510(k) No.		K123988	K211812
Device Name	**Abutment Screw**	**Abutment Screw**	**Abutment Screw**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The BLUEDIAMOND IMPLANT System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose ofproviding prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. These implants can be used where smaller implants have failed.
Design			
Diameter (Ø)	2.0, 2.1, 2.2 mm	2.3mm	2.2 mm
Total Length	7.9 ~ 12.7 mm	10.1 mm	9.9 mm
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined, Anodizing	Machined	Machined, Anodizing
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Abutment Screw is used for connecting abutment for each Implant System. The lower part has male screws depending on the fixture system to be connected.	Abutment screw is used for is used for connecting the Abutment to the fixture.	The Abutment Screw is used for connecting Fixture to Abutment or Abutment to Cylinder.
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUDIAMOND Implant System	AnyOne Internal Implant System	BLUDIAMOND Implant System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Material, Surface Treatment, Single Use, Sterilization, Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference device.

- Diameter

  Some of the diameters (2.0, 2.1 mm) of the subject device are smaller than the reference devices while other diameter (2.2 mm) is same with the reference devices. The difference in size is very small, so the issue of substantive equivalence does not arise. And the variety of sizes allows for more precise treatment tailored to each patient's condition.

- Total Length

  The Total Length of the subject device is slightly different with the reference devices but it does not cause a matter in substantial equivalence since the size differences are very minor.

3. Discussion

The subject device and reference devices have common in Indication for use, Design, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation. The differences are explained not affecting on the substantial equivalence.

- Based on the information based in submission, we conclude that the subject device is substantially equivalent to the reference devices.

(16) Cylinder Screw

	Subject Device	Reference Device	
510(k) No.	-	K203808	K123988
Device Name	**Cylinder Screw**	**Cylinder Screw**	**Flat Cylinder Screw**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The Multi-unit Abutment, Multi-unit Angled Abutment is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.
Design			
Diameter (Ø)	2.1 mm	2.0 mm	2.1 mm
Total Length	4.2 ~ 4.65 mm	3.4mm	5.9 mm
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Machined
Single Use	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	Cylinder Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment or AXA Abutment to Healing Cap, Temporary cylinder or EZ Post Cylinder or CCM Cylinder. It is made of Ti-6Al-4V-ELI and offered in machined surface. The Cylinder Screw is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.	Cylinder Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to healing cap, Temporary Cylinder or CCM Cylinder.	Flat Cylinder Screw is used for connecting Abutment to healing cap or Cylinder.
Compatible Implant System	XPEED AnyRidge Internal Implant System AnyOne Internal Implant System BLUDIAMOND Implant System	XPEED AnyRidge Internal Implant System BLUDIAMOND Implant System AnyOne Internal Implant System	AnyOne Internal Implant System

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Diameter, Material, Surface Treatment, Single Use, Sterilization, Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Total Length

The Total Length of subject device is slightly different with the reference devices. The Total Length of subject device is slightly different with the reference devices. Therefore, it does not cause a matter in substantial equivalence since this size difference is very minor.

3. Discussion

The subject device and reference devices have common in all the items except the Total Length. The Total Length difference is explained not affecting on the substantial equivalence.

- Based on the information based in submission, we conclude that the subject device is substantially equivalent to the reference devices.

(17) Crown Screw

	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.		K182448	K103280	K133377
Device Name	**Crown Screw**	**Multi-unit Abutment Screw**	**Rosen Screw**	**Omniqrip Clinical Screw**
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	BHI IMPLANTS LTD	Nobel Biocare
Indications for Use Statement	The MegaGen Dental Implant Abutment is intended to be surgically placed in the maxillary or mandibular areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patients chewing function. All digitally designed abutments for use with ZrGEN Abutment are intended to be sent to a MegaGen validated milling center for manufacture.	The AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	The Bhdental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient chewing function. The Bhdental Implant is also indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The NobelProcera Angulated Screw Channel Abutment Replace are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.
Design				
Diameter (Ø)	2.1, 2.3, 2.4 mm	2.1 mm	1.4, 1.6, 1.72 mm	Unknown
Total Length	4.65, 5.2, 7.2 mm	7.0 mm	Unknown	Unknown
Material	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)	Ti-6Al-4V ELI (ASTM F136-13)
Surface Treatment	Machined	Machined	Machined, Anodizing	Machined, Anodizing
Single Use	Yes	Yes	Yes	Yes
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of Operation	The Crown Screw is a prosthetic component connected to abutment and intended for use as an aid in prosthetic rehabilitaion. It is made of Ti-6Al-4V-ELI and offered in machined surface. The crown Screw is supplied non-sterile, to be sterilized by the user according to the IFU and intended for single use.	Multi-unit Abutment Screw is used for connecting Multi-unit Abutment or Multi-unit Angled Abutment to the fixture.	The Bhdental Implnat System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for ptosthetic devices, such as artificial teeth, in order to restore the patient chewing function.	The NobelProcera Angulated Screw Channel Abutment Replace are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation.
Compatible Implant System	XPEED AnyRidge Internal Implant System BLUDIAMOND Implant System AnyOne Internal Implant System	BLUDIAMOND Implant System	N/A	N/A

Substantial Equivalence Discussion

1. Similarities

The subject device has the same characteristic for the followings compared to the reference devices.

- Indication for use, Design, Material, Surface Treatment, Single Use, Sterilization, Principle of Operation

2. Differences

The subject device has the different characteristic for the followings compared to the reference devices.

- Diameter

The Diameter (2.1mm) of the subject device is same with the dimeter of reference device 1 and the others are different.
And the Diameter of reference device 3 is unknown. The differences are very minor with the reference device 1 therefore it does not cause a matter in substantial equivalence.

- Total Length

The Total lengths of reference devices 1, 2 are unknown. The total length (7.2 mm) of the subject device is slightly different with the reference device 1. But the total length includes the connection length of each implant system and therefore does not affect substantial equivalence.

3. Discussion

The subject device and reference devices have common in Indication for use, Design, Material, Surface Treatment, Single Use, Sterilization and Principle of Operation. The Diameter and Total length differences are explained not affecting on the substantial equivalence.

- Based on the information based in submission, we conclude that the subject device is substantially equivalent to the reference devices.

8. Summary of Non-Clinical Testing

The non-clinical testing data which are submitted, referenced, or relied on in this submission support demonstrating substantial equivalence.

Biocompatibility

The biocompatibility evaluation has been performed in accordance with International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
All of the subject device materials and manufacturing have been previously cleared in K182448 and K231967. Therefore, no additional biocompatibility testing was performed in this submission.

Sterilization validation

The Scan Healing Abutment is provided as sterile device. The sterile device is cleaned and sterilized by gamma irradiation. The final sterilization process, γ-ray irradiation is commissioned to an outside company specializing in it. The Sterility Assurance Level (SAL) shall comply with EN556, that is the Highest Assurance Level (Class 3), 10-6. γ-sterilization doze shall be set based on this and for γ-sterilization doze, sterilization doze and irradiation shall be determined in accordance with ISO11137-Method I.

The subject devices excluding the sterile device are supplied in non-sterile state. Sterilization validating testing for steam sterilization by the user has been performed in accordance with ISO 11137 and ISO 17665-1, 2 to verify the sterility assurance level (10^{-6}).

Performance (Physical Properties) Test

The bench tests have been performed in accordance with 'ISO 14801' and the recommendations of 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment' to evaluate the performance of the subject devices and the test results met the pre-set criteria.

MR Compatibility

Non-clinical worst-case MRI review was performed to evaluate the metallic MegaGen Dental Implant system as MR Conditional in the MRI environment using scientific rationale and published literature (Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment", including magnetically induced displacement force and torque.

Summary of Clinical Testing

No clinical studies are submitted.

Conclusion

Based on the information provided in this premarket notification, We, MegaGen Implant Co., Ltd. conclude that the MegaGen Dental Implant Abutment is substantially equivalent to the predicate device as herein.