December 7, 2023

MegaGen Implant Co., Ltd.
Kyung-Hee Back
Official Correspondent
45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun
Daegu, 42921
REPUBLIC OF KOREA

Re: K231967
Trade/Device Name: ARi ExCon Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 2, 2023
Received: November 2, 2023

Dear Kyung-Hee Back:

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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K231967

Device Name
ARi ExCon Implant System

Indications for Use *(Describe)*
The ARi ExCon 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 situations and with the clinical protocols:
- Delayed loading
- Immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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.

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.**

## V. 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR Part 807.92.

Date: December 6, 2023

### 1. Applicant / Submitter

MegaGen Implant Co., Ltd.
45, Secheon-ro, 7-gil, Dasa-eup, Dalseong-gun,
Daegu, Republic of Korea
Tel: + 82-53-222-2828

### 2. Submission Correspondent

Kyung-Hee Back
MegaGen Implant Co., Ltd.
45, Secheon-ro, 7-gil, Dasa-eup, Dalseong-gun,
Daegu, Republic of Korea
Tel: +82-53-222-3864 Fax: +82-53-289-3414
Email: ra9@imegagen.com

### 3. Device

- Trade Name: ARi ExCon Implant System
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Primary Product Code: DZE
- Secondary Product Code: NHA
- Classification regulation: Class II, 21 CFR 872.3640

### 4. Predicate Device

- **Primary Predicate Device:**
  K163634 - External Hex Implants

- **Reference Device:**
  K210852 - Noris Medical Dental Implants System – Cortical
  K200586 - Straumann TLX Implant System – TLX S
  K203554 - AnyOne External Implant System
  K182448 - BLUEDIAMOND IMPLANT System
  K150537 - MiNi Internal Implant System
  K123988 - AnyOne Internal Implant System
  K110955 - AnyRidge Internal Implant System
  K192347 - ST Internal Implant System
  K210161 - AnyOne Onestage Implant System
  K220562 - TiGEN Abutment, ZrGEN Abutment and Scan Healing Abutment
  K122231 - XPEED AnyRidge Implant System
  K230618 - MegaGen Dental Implant Systems Portfolio – MR Conditional

## 5. Description

- The ARi ExCon Implant is a substructure of a dental implant system made of CP Ti Grade 4 with the surface treated by SLA method. It is intended to be placed in the maxillary or mandibular areas to restore masticatory function.
  The Abutments are prosthetic components directly or indirectly connected to the endosseous dental implant and are intended for use as an aid in prosthetic rehabilitation, allows single & multiple prosthetic restorations.

- The **ARi ExCon Implant System** is consisted of the following components.

| Device | | Content | |
|---|---|---|---|
| 1. Fixture | ARi ExCon Implant | Description | The ARi ExCon Implant is a substructure of a dental implant system made of CP Ti Grade 4 with the surface treated by SLA method. It is intended to be placed in the maxillary or mandibular areas to restore masticatory function. |
| | | Material | CP Ti Grade 4 of ASTM F67 |
| | | Dimension (Diameter & Total Length) | · Normal Thread<br>Ø 3.8 x 11.0, 13.0, 15.0 mm<br>Ø 4.3 x 11.0, 13.0, 15.0 mm<br>Ø 4.8 x 11.0, 13.0, 15.0 mm<br>Ø 5.3 x 11.0, 13.0, 15.0 mm<br>· Deep Thread<br>Ø 4.3 x 11.0, 13.0, 15.0 mm<br>Ø 4.8 x 11.0, 13.0, 15.0 mm<br>Ø 5.3 x 11.0, 13.0, 15.0 mm<br>Ø 5.8 x 11.0, 13.0, 15.0 mm |
| 2. Prosthetics | Cover Screw | Description | The Cover Screw is used in conjunction with fixture for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement. |
| | | Material | Ti-6Al-4V ELI of ASTM F136-13 |
| | | Dimension (Diameter & Total Length) | Ø 2.6 x 3.1 mm<br>Ø 3.2 x 3.1 mm<br>Ø 3.4 x 3.6, 4.1, 5.1 mm<br>Ø 4.0 x 3.6, 4.1, 5.1 mm |
| | | Angulation | Straight |
| | Healing Abutment | Description | The Healing Abutment is used in conjunction with fixture and helps to form suitable emergence profile during period of gingival healing. |
| | | Material | Ti-6Al-4V ELI of ASTM F136-13 |
| | | Dimension (Diameter & Total Length) | Ø 3.7 x 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 11.0 mm<br>Ø 4.2 x 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 11.0 mm<br>Ø 5.2 x 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 11.0 mm<br>Ø 6.2 x 5.0, 6.0, 7.0, 8.0, 9.0, 10.0, 11.0 mm |
| | | Angulation | Straight |
| | Scan Healing Abutment | Description | The Scan Healing Abutment is used 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. |
| | | Material | Ti-6Al-4V ELI of ASTM F136-13 |
| | | Dimension (Diameter & Total Length) | Ø 4.2 x 4.5, 5.5, 7.5, 9.5 mm<br>Ø 4.7 x 4.5, 5.5, 7.5, 9.5 mm<br>Ø 5.7 x 4.5, 5.5, 7.5, 9.5 mm |
| | | Angulation | Straight |
| | S.H.A Screw | Description | At the top of the S.H.A Screw, an internal hex groove is processed so that it can be fastened with a driver, and at the bottom, a thread is formed so that it can be fastened with the internal female screw of the fixture. |
| | | Material | Ti-6Al-4V ELI of ASTM F136-13 |
| | | Dimension (Diameter & Total Length) | Ø 2.0 x 5.33, 6.33, 8.33, 10.33 mm |
| | | Angulation | Straight |
| | Temporary Abutment | Description | The Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration. |
| | | Material | Ti-6Al-4V ELI of ASTM F136-13 |
| | | Dimension (Diameter & Total Length) | Ø 3.5, 4.0, 4.5 x 12.0 mm<br>Ø 3.5 x 10.0, 12.0, 14.0 mm<br>Ø 3.5, 4.0, 5.0, 6.0 x 10.0 mm |
| | | Angulation | Straight |

<table>
<tr><td rowspan="15"></td><td rowspan="4">EZ Post Abutment</td><td>Description</td><td>The EZ Post Abutment is used in conjunction with fixture to provide support for cement and screw retained type final prosthesis.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V ELI of ASTM F136-13</td></tr>
<tr><td>Dimension (Diameter & Total Length)</td><td>Ø 3.5 x 7.0, 8.0, 9.0, 10.0, 11.0, 12.0 mm<br>Ø 4.0 x 7.0, 8.0, 9.0, 10.0, 11.0, 12.0 mm<br>Ø 5.0 x 7.0, 8.0, 9.0, 10.0, 11.0, 12.0 mm<br>Ø 6.0 x 7.0, 8.0, 9.0, 10.0, 11.0, 12.0 mm</td></tr>
<tr><td>Angulation</td><td>Straight</td></tr>
<tr><td rowspan="4">Angled Abutment</td><td>Description</td><td>The Angled Abutment is used in conjunction with fixture and used for correcting the prosthetic angulation of implant.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V ELI of ASTM F136-13</td></tr>
<tr><td>Dimension (Diameter & Total Length)</td><td>Ø 4.0 x 9.0, 10.0, 11.0, 12.0 mm<br>Ø 5.0 x 9.0, 10.0, 11.0, 12.0 mm<br>Ø 6.0 x 9.0, 10.0, 11.0, 12.0 mm</td></tr>
<tr><td>Angulation</td><td>15˚, 25˚</td></tr>
<tr><td rowspan="4">Solid Abutment</td><td>Description</td><td>The Solid Abutment is used in conjunction with fixture to provide support for final prosthesis, and used in cement retained type prosthesis only.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V ELI of ASTM F136-13</td></tr>
<tr><td>Dimension (Diameter & Total Length)</td><td>Ø 2.3 x 7.9, 9.9, 11.9 mm</td></tr>
<tr><td>Angulation</td><td>Straight</td></tr>
<tr><td rowspan="4">ZrGEN Abutment</td><td>Description</td><td>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.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V ELI of ASTM F136-13</td></tr>
<tr><td>Dimension (Diameter & Total Length)</td><td>Ø 4.0 x 6.5, 7.5, 8.0, 8.5, 9.0, 10.0, 11.0, 12.0 mm<br>Ø 4.5 x 6.5, 7.5, 8.0, 8.5, 9.0, 10.0, 11.0, 12.0 mm<br><br>The allowable ranges of design parameters are follows:
<table>
<tr><td rowspan="5">Titanium base</td><td>Minimum wall thickness (mm)</td><td>0.5</td></tr>
<tr><td>Minimum gingival collar (ø)</td><td>4.0</td></tr>
<tr><td>Maximum gingival collar (ø)</td><td>4.5</td></tr>
<tr><td>Minimum post height (mm)</td><td>4.5</td></tr>
<tr><td>Maximum post height (mm)</td><td>8.0</td></tr>
</table>
The allowable ranges of design parameters after CAD/CAM patient-matching are follows:
<table>
<tr><td rowspan="7">Zirconia top-half</td><td>Minimum wall thickness (mm)</td><td>0.5</td></tr>
<tr><td>Minimum gingival collar (ø)</td><td>8</td></tr>
<tr><td>Maximum gingival collar (ø)</td><td>10</td></tr>
<tr><td>Minimum gingival collar height (mm)</td><td>2</td></tr>
<tr><td>Maximum gingival collar height (mm)</td><td>5</td></tr>
<tr><td>Minimum post height (mm)</td><td>7</td></tr>
<tr><td>Maximum post height (mm)</td><td>15</td></tr>
</table></td></tr>
<tr><td>Angulation</td><td>Straight</td></tr>
<tr><td rowspan="3">TiGEN Abutment</td><td>Description</td><td>The TiGEN Abutment is machined with the final prosthetic in accordance with the intraoral structure.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V ELI of ASTM F136-13</td></tr>
<tr><td>Dimension (Diameter & Total Length) & Angulation</td><td>Ø 10.0, 12.0 x 26.0 mm<br><br>The allowable ranges of design parameters after CAD/CAM patient-matching are follows:
<table>
<tr><td rowspan="8">Standard Type</td><td>Minimum wall thickness (mm)</td><td>0.05</td></tr>
<tr><td>Maximum angulation (°)</td><td>30</td></tr>
<tr><td>Minimum gingival collar height (mm)</td><td>4.00</td></tr>
<tr><td>Maximum gingival collar height (mm)</td><td>5.00</td></tr>
<tr><td>Minimum gingival collar (ø)</td><td>4.00</td></tr>
<tr><td>Maximum gingival collar (ø)</td><td>9.50, 11.50</td></tr>
<tr><td>Minimum post height (mm)</td><td>4.00</td></tr>
<tr><td>Maximum post height (mm)</td><td>6.00</td></tr>
</table></td></tr>
<tr><td rowspan="3">Abutment Screw</td><td>Description</td><td>The Abutment Screw is used for securing the abutment to the endosseous implant.</td></tr>
<tr><td>Material</td><td>Ti-6Al-4V ELI of ASTM F136-13</td></tr>
<tr><td>Dimension (Diameter & Total Length)</td><td>Ø 2.5 x 5.1 mm</td></tr>
</table>

## 6. Indication for use

The ARi ExCon 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 situations and with the clinical protocols:

- Delayed loading
- Immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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.

## 7. Basis for Substantial Equivalence

The ARi ExCon Implant System are 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.

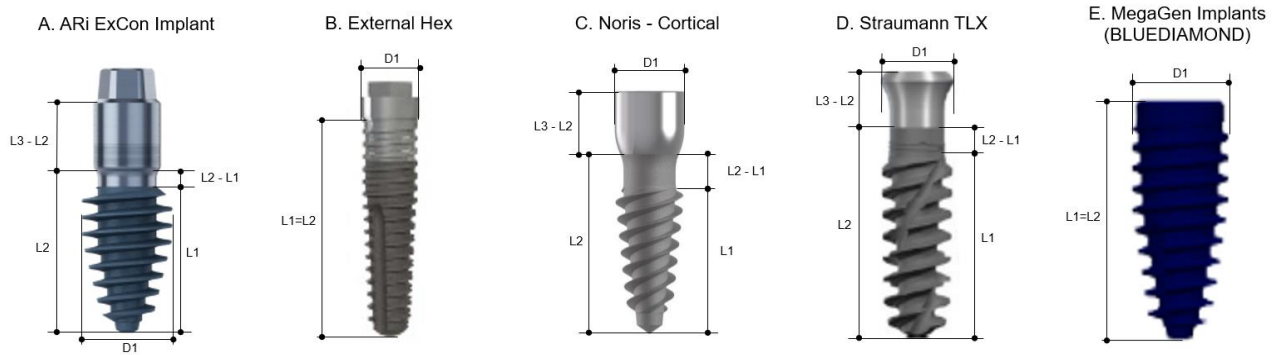
Based on the technological characteristic comparison tables below and test results provided in this submission, we conclude that the subject device is substantially equivalent to the predicate device.

**TABLE 1 - TECHNOLOGICAL CHARACTERISTIC COMPARISON TABLE**

**ARi ExCon Implant**

**Dimensions of the implants (Subject, Predicate and Reference devices)**

(A) ARi ExCon Implant – Subject device (B) External Hex – Predicate device (C) Noris – Cortical – Ref. 1 (D) Straumann TLX – Ref. 2 (E) MegaGen Implants – Ref. 4




| | Subject Device | Predicate Device | Reference Device 1 | Reference Device 2 | Reference Device 3 | Reference Device 4 | Reference Device 5 |
|---|---|---|---|---|---|---|---|
| **510k** | K231967 | K163634 | K210852 | K200586 | K203554 | K182448 | K122231 |
| **Device Name** (Compatible Implant System) | **ARi ExCon Implant** For ARi ExCon Implant System | **External Hex Implants** For External Hex Implants | **Noris Medical Dental Implants** For Noris Medical Dental Implants System - Cortical | **Straumann TLX** Straumann TLX Implant System – TLX S | **AnyOne External Fixture** For AnyOne External Implant System | **BLUEDIAMOND IMPLANT** For BLUEDIAMOND IMPLANT System | **XPEED AnyRidge Internal Fixture** For XPEED AnyRidge Internal Implant System |

| **Manufacturer** | MegaGen Implant Co., Ltd. | Southern Implants (Pty) Ltd. | Noris Medical LTD | Institut Straumann AG | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. |
|---|---|---|---|---|---|---|---|
| **Indication for use** | The ARi ExCon 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 situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal loading. | Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading.<br>Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved. | Noris Medical Dental Implants System is intended to replace missing tooth/teeth in either jaw for supporting prosthetic devices that may aid in restoring the patient's chewing function. The procedure can be accomplished in a one-stage or two-stage surgical operation. All implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. | Straumann TLX Implants are suitable for endosteal implantation in the upper and lower jaws and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. TLX Implants can be placed with immediate function on single-tooth and multi-unit restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function. The prosthetic restorations are connected to the implants through the corresponding abutment components. | The AnyOne External 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 IMPLNAT System is intended to be surgically placed in the maxillary or mandibular molar arches 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 chewing function in the following situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region. | 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 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. |
| **Design** |  |  |  |  |  |  |  |
| **Widest Thread Diameter (D1) (Ø) & Total Length (L3) (mm)** | · Normal Thread<br>Ø 3.8 x 11.0, 13.0, 15.0<br>Ø 4.3 x 11.0, 13.0, 15.0<br>Ø 4.8 x 11.0, 13.0, 15.0<br>Ø 5.3 x 11.0, 13.0, 15.0<br><br>· Deep Thread<br>Ø 4.3 x 11.0, 13.0, 15.0<br>Ø 4.8 x 11.0, 13.0, 15.0<br>Ø 5.3 x 11.0, 13.0, 15.0 | Ø3.25 x 8.5, 10.0, 11.5, 13.0, 15.0, 18.0<br>Ø4.0 x 6.0, 8.5, 10.0, 11.5, 13.0, 15.0, 18.0, 20.0<br>Ø4.0 x 6.0, 8.5, 10.0, 11.5, 13.0, 15.0<br>Ø4.7x 10.0, 11.5, 13.0, 15.0, 18.0<br>Ø5.0 x 6.0, 8.5, 10.0, | Ø4.0 X 11.5, 13.0, 16.0, 18.0, 20.0<br>Ø5.0 X 11.5, 13.0, 16.0<br>Ø6.0 X 11.5, 13.0, 16.0 | Ø3.75 X 6.0, 8.0, 10.0, 12.0, 14.0, 16.0, 18.0<br>Ø4.0 X 6.0, 8.0, 10.0, 12.0, 14.0, 16.0, 18.0<br>Ø4.5 X 6.0, 8.0, 10.0, 12.0, 14.0, 16.0, 18.0<br>Ø5.0 X 6.0, 8.0, 10.0, 12.0, 14.0, 16.0, 18.0<br>Ø5.5 X 6.0, 8.0, 10.0, 12.0<br>Ø6.5 X 6.0, 8.0, 10.0, 12.0 | Ø3.9 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5<br>Ø4.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5<br>Ø4.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5<br>Ø5.3 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5<br>Ø5.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5<br>Ø6.3 x 7.0, 8.0, 9.5, 11.0, | · Normal thread<br>Ø3.6 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø4.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø4.4 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø4.7 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø5.0 X 7.0, 7.7, 9.2, 10.7, | · Normal thread<br>Ø4.0 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø4.4 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø4.9 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø5.4 X 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø5.9 X 7.7, 9.2, 10.7, 12.2, |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Ø 5.8 x 11.0, 13.0, 15.0 | 11.5, 13.0, 15.0, 18.0<br>Ø 5.7 x 10.0, 11.5, 13.0, 15.0, 18.0<br>Ø 6.0 x 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 | | | 12.5, 14.5<br>Ø6.8 x 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 | 12.2, 14.2, 17.2<br><br>· Deep thread<br>Ø4.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø4.4 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø4.8 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø5.0 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2<br>Ø5.5 X 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 | 14.2, 17.2<br><br>· Deep thread<br>Ø6.4 X 7.9, 9.4, 10.9, 12.4, 14.4<br>Ø6.9 X 7.9, 9.4, 10.9, 12.4, 14.4<br>Ø7.4 X 7.9, 9.4, 10.9, 12.4, 14.4<br>Ø7.9 X 7.9, 9.4, 10.9, 12.4, 14.4<br>Ø8.4 X 7.9, 9.4, 10.9, 12.4, 14.4 |
| **Threaded Length (mm) (L1)** | For all diameters: 7.0, 9.0 | Unknown | For Ø4.0: 6.8, 8.0, 10.0, 11.0, 12.5<br>For Ø5.0: 6.8, 8.0, 10.0<br>For Ø6.0: 6.8, 8.0, 10.0 | For Ø3.75, 4.5: 7.0, 8.3, 10.3, 12.3, 14.0, 16.0<br>For Ø5.5: 7.0, 8.3, 10.3 | For all diameters: 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 | For all diameters: 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 | For all diameters: 7.7, 7.9, 9.2, 9.4, 10.7, 10.9, 12.2, 12.4, 14.2, 14.4, 17.2 |
| **Implanted Length (mm) (L2)**<br>(Length within the bone) | For all diameters: 8.0, 9.0, 10.0, 11.0 | Unknown | For Ø4.0: 7.5, 9.0, 12.0, 14.0, 16.0<br>For Ø5.0: 7.5, 9.0, 12.0<br>For Ø6.0: 7.5, 9.0, 12.0 | For Ø3.75, 4.0, 4.5, 5.0: 6.0, 8.0, 10.0, 12.0, 14.0, 16.0, 18.0<br>For Ø5.5, 6.5: 6.0, 8.0, 10.0, 12.0 | For all diameters: 7.0, 8.0, 9.5, 11.0, 12.5, 14.5 | For all diameters: 7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 | For all diameters: 7.7, 7.9, 9.2, 9.4, 10.7, 10.9, 12.2, 12.4, 14.2, 14.4, 17.2 |
| **Gingival (Cuff) Height (mm) (L3-L2)** | 3.0, 4.0 | N/A | 4.0 | 3.3 | N/A | N/A | N/A |
| **Thread to Shoulder Height (mm) (L2-L1)** | For L8.0: 1.0<br>For L9.0: 2.0<br>For L10.0: 1.0<br>For L11.0: 2.0 | N/A | For L7.5: 0.7<br>For L9.0: 1.0<br>For L12.0: 2.0<br>For L14.0: 3.0<br>For L16.0: 3.5 | For L8.0: 1.0<br>For L10.0, L12.0. L14.0: 1.7<br>For L16.0, L18.0: 2.0 | N/A | N/A | N/A |
| **Implant to Abutment Connection** | External Hex | External Hex | Internal Hex | TorcFit<br>(with conical fitting) | External Hex | Internal Octa | Internal Hex |
| **Material** | CP Ti Grade 4<br>(ASTM F67) | CP Ti Grade 4<br>(ASTM F67) | Titanium alloy | Titanium-13 Zirconium alloy (Roxolid®) | CP Ti Grade 4<br>(ASTM F67) | CP Ti Grade 4<br>(ASTM F67) | CP Ti Grade 4<br>(ASTM F67) |
| **Surface Treatment** | Sand-blasted, Large grit, Acid-etched (S.L.A)<br>Machined collar | Grit blasted<br>Machined collar | RBM | Hydrophilic SLActive® | Sand-blasted, Large grit, Acid-etched (S.L.A) | Sand-blasted, Large grit, Acid-etched (S.L.A) | Sand-blasted, Large grit, Acid-etched (S.L.A) |
| **Sterilization** | Sterile – irradiation | Sterile – irradiation | Sterile – irradiation | Sterile – irradiation | Sterile – irradiation | Sterile – irradiation | Sterile – irradiation |
| **Shelf Life** | 5 Years | 5 Years | 5 Years | 5 Years | 5 Years | 5 Years | 5 Years |
| **Feature** | - Tapered body<br>- 0.8mm thread pitch | - Tapered body<br>- Threaded | - Tapered body<br>- Threaded | - Tapered body | - Tapered body<br>- cutting edge with self-tapping<br>- 0.8mm thread pitch | - Tapered body<br>- cutting edge with self-tapping<br>- 0.8mm thread pitch | - Tapered body<br>- 0.8 ~ 1.55mm thread pitch |
| **Substantial Equivalence Discussion** | | | | | | | |
| **1. Similarities**<br>The subject device has the same characteristic for the followings compared to the Predicate device. | | | | | | | |

- Indication for Use, Design, Implant to Abutment Connection, Material, Sterilization and Shelf-life.

**2. Differences**

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

- Widest Thread Diameter, Total Length

The Widest Thread Diameter and Total Length of subject device is slightly different with predicate device but all the dimensions of subject device lie within range of predicate device. It does not affect substantial equivalence.

- Threaded Length

The Threaded Length of the Predicate device is unknown. But, all dimensions of subject device lie within range of Reference devices (1, 2, 3, 4). It does not affect substantial equivalence.

- Implanted Length

The Implanted Length of the Predicate device is unknown. But, all dimensions of subject device lie within range of Reference devices (1, 2, 3, 4, 5). It does not cause a matter in substantial equivalence.

- Gingival (Cuff) Height

The Gingival (Cuff) Height of the Predicate device is unknown. But, all dimensions of subject device lie within range of Reference devices (1, 2). It does not cause a matter in substantial equivalence.

- Thread to shoulder Height

Thread to shoulder Height of the Predicate device is unknown. But, all dimensions of subject device lie within range of Reference device 1. The variety of the size can be possible to operate more precise treatment to meet each patient's condition. It does not affect substantial equivalence.

- Surface Treatment

The subject device is treated with Sand-blasted, Large grit, Acid-etched (S.L.A) while the predicate device is treated with Grit blasted, but has same Surface Treatment as reference device 3, 4, and 5. Subject device and predicate device has machined collar.

- Feature

The subject device has Tapered Body, 0.8mm thread pitch while the predicate device has Tapered Body and Threaded feature, but has same Feature as reference device 3, and 4.

**3. Discussion**

The proposed ARi ExCon Implant have common in all the terms in the comparison chart except the Widest Thread Diameter, Total Length, Threaded Length, Implanted Length, Gingival (Cuff) Height, Thread to shoulder Height, Surface Treatment and Feature. But all dimensions of subject device lie within range of Predicate/Reference devices.

The fatigue test was performed on worst case to confirm the substantial equivalence according to "ISO 14801" and "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment". The test result supports that the subject device is substantially equivalent to the predicate device and the differences are not affecting the substantial equivalence.

On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the Predicate device.

## Cover Screw

| | Subject Device | Predicate Device | Reference Device 1 | Reference Device 2 |
|---|---|---|---|---|
| **510k** | K231967 | K163634 | K150537 | K203554 |
| **Device Name (Compatible Implant System)** | **Cover Screw** For ARi ExCon Implant System | **Cover Screw** For External Hex Implants | **Cover Screw** For MiNi Internal Implant System | **Cover Screw** For AnyOne External Implant System |
| **Manufacturer** | MegaGen Implant Co., Ltd. | Southern Implants (Pty) Ltd. | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 situations and with the clinical protocols: - Delayed loading - Immediate loading when good primary stability is achieved and with appropriate occlusal loading. | Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved. | The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols: - The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.- It is intended for delayed loading. | The AnyOne External 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, mm)** | 2.6, 3.2, 3.4, 4.1 | 3.5, 5.0 | 2.6, 3.5 | 3.5, 4.1, 5.0 |
| **Total Length (mm)** | 3.1, 3.6, 4.1, 5.1 | 4.35, 4.4 | 3.1 ~ 10.25 | 5.3, 6.2 |
| **Connection Interface** | Conical Connection | Conical Connection | Conical Connection | Conical Connection |
| **Material** | Ti-6Al-4V ELI (ASTM F136-13) | CPTi, Titanium alloy, Gold, CoCr | Ti-6Al-4V ELI (ASTM F136-13) | Ti-6Al-4V ELI (ASTM F136-13) |
| **Surface Treatment** | Anodizing | Machined, Anodizing | Anodizing, Machined | Anodizing, Machined |
| **Single Use** | Yes | Yes | Yes | Yes |
| **Sterilization** | Sterile – irradiation | Sterile – irradiation | Sterile – irradiation | Sterile – irradiation |

**Substantial Equivalence Discussion**

1. **Similarities**

The subject device has the same characteristic for the followings compared to the prior cleared Predicate device.
- Indication for use, Design, Connection Interface, Surface Treatment, Single Use and Sterilization.

2. **Difference**

The subject device has the different characteristic for the followings compared to the Predicate device.
- Diameter

The Diameter of subject device is slightly different with Predicate device, but the diameter is within the bounds of the cleared predicate and the reference devices. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.
- Total Length

The Total Length of subject device is slightly different with the prior cleared Predicate device, but all dimensions of subject device lie within range of the prior cleared Reference devices. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.
-Material

The raw materials of the predicate device identified from K163634 are CPTi, Titanium alloy, Gold, CoCr, which also includes the subject device's raw material (titanium alloy). Also, the raw materials of subject device are equivalent to the MegaGen's cleared reference devices.

3. **Discussion**

The proposed Cover Screw and Predicate device have common in all the terms in the comparison chart except the Diameter, Total Length, Material.

However, these differences are not affect device's fundamental functions and safety. Therefore, it is substantial equivalent.

On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the Predicate device.

## Healing Abutment

| | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| **510k** | K231967 | K163634 | K182448 |
| **Device Name (Compatible Implant System)** | **Healing Abutment**<br>For ARi ExCon Implant System | **Healing Abutment**<br>For External Hex Implants | **Healing Abutment**<br>For BLUEDIAMOND IMPLANT System |
| **Manufacturer** | MegaGen Implant Co., Ltd. | Southern Implants (Pty) Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal loading. | Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading.<br>Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved. | The BLUEDIAMOND IMPLANT System 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:<br>-Delayed loading.<br>-Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region. |
| **Design** |  |  |  |
| **Diameter (Ø, mm)** | 3.7, 4.2, 5.2, 6.2 | 4.5, 5.5, 6.5, 7.5 | 3.2, 4.2, 5.2, 6.2 |
| **Post Height(mm)** | 3.5, 4.5, 5.5, 6.5, 7.5, 8.5, 9.5 | 2.2, 3.0, 4.0, 5.0, 6.0, 8.0, 12.0 | 2.5, 3.5, 4.5, 5.5, 6.5, 7.5, 8.5, 9.5 |
| **Angulation** | Straight | Straight | Straight |
| **Connection Interface** | Conical Connection | Conical Connection | Conical Connection |
| **Material** | Ti-6Al-4V ELI<br>(ASTM F136-13) | CPTi, Titanium alloy, Gold, CoCr | Ti-6Al-4V ELI<br>(ASTM F136-13) |
| **Surface Treatment** | Anodizing | Machined, Anodizing | Anodizing |
| **Single Use** | Yes | Yes | Yes |
| **Sterilization** | Sterile – irradiation | Sterile – irradiation | Sterile – irradiation |

**Substantial Equivalence Discussion**

**1. Similarities**

The subject device has the same characteristic for the followings compared to the prior cleared Predicate device.

- Indication for use, Design, Angulation, Connection Interface, Surface Treatment, Single Use and Sterilization.

**2. Difference**

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

- Diameter

The Diameter of subject device is slightly different with the prior cleared the Predicate device. But, The diameter lies within range of the prior cleared Reference device.

- Post Height

The Post Height of subject device is slightly different with the prior cleared the Predicate device. But all of post height are the same as the post height of the prior cleared reference devices.

-Material

The raw materials of the predicate device identified from K163634 are CPTi, Titanium alloy, Gold, CoCr, which also includes the subject device's raw material (titanium alloy). Also, the raw materials of subject device are equivalent to the MegaGen's cleared reference device.

**3. Discussion**

The proposed Healing Abutment and Predicate device have common in all the terms in the comparison chart except the Diameter, Post Height, Material.

However, these differences are not affect device's fundamental functions and safety. Therefore, it is substantial equivalent.

## Scan Healing Abutment

| | Subject Device | Reference Device |
|---|---|---|
| **510k** | K231967 | K220562 |
| **Device Name (Compatible Implant System)** | **Scan Healing Abutment**<br>For ARi ExCon Implant System | **Scan Healing Abutment**<br>For MegaGen's Implant systems |
| **Manufacturer** | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal 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. |
| **Design** |  |  |
| **Diameter (Ø, mm)** | 4.2, 4.7, 5.7 | 4.2, 4.7, 5.7, 6.7 |
| **Post Height (mm)** | 3.0 | 2.5, 3.5, 4.5, 5.5, 6.5, 7.5, 8.5, 9.5 |
| **Angulation** | Straight | Straight |
| **Connection Interface** | Conical Connection | Conical Connection |
| **Material** | Ti-6Al-4V ELI<br>(ASTM F136-13) | Ti-6Al-4V ELI<br>(ASTM F136-13) |
| **Surface Treatment** | Anodizing and Machined | Anodizing |
| **Single Use** | Yes | Yes |
| **Sterilization** | Sterile – irradiation | Sterile – irradiation |

**Substantial Equivalence Discussion**

**1. Similarities**

The subject device has the same characteristic for the followings compared to the prior cleared Reference device.

- Indication for use, Design, Diameter, Angulation, Connection Interface, Material, Surface Treatment, Single Use and Sterilization.

**2. Difference**

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

- Post Height

The Post Height of subject device is slightly different with the prior cleared the Reference device. But, The Post Height lies within range of the prior cleared Reference device.

**3. Discussion**

The proposed Scan Healing Abutment and Reference device have common in all the terms in the comparison chart except the Post Height. However, these differences are not affect device's fundamental functions and safety. Therefore, it is substantial equivalent.

## S.H.A Screw

| | Subject Device | Reference Device |
|---|---|---|
| **510k** | K231967 | K220562 |
| **Device Name (Compatible Implant System)** | **S.H.A Screw**<br>For ARi ExCon Implant System | **S.H.A Screw**<br>For MegaGen's Implant systems |
| **Manufacturer** | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal 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. |
| **Design** |  |  |
| **Diameter (Ø, mm)** | 2.0 | 1.95, 2.0, 2.1 |
| **Total Length (mm)** | 5.33, 6.33, 8.33, 10.33 | 9.4, 9.8, 10.4, 10.6, 10.8, 11.6, 12.4, 12.8, 13.6 |
| **Material** | Ti-6Al-4V ELI<br>(ASTM F136-13) | Ti-6Al-4V ELI<br>(ASTM F136-13) |
| **Surface Treatment** | Anodizing and Machined | Anodizing and Machined |
| **Single Use** | Yes | Yes |
| **Sterilization** | Sterile – irradiation | Sterile – irradiation |

**Substantial Equivalence Discussion**

**1. Similarities**

The subject device has the same characteristic for the followings compared to the prior cleared Reference device.

- Indication for use, Design, Diameter, Material, Surface Treatment, Single Use and Sterilization.

**2. Difference**

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

- Total Length

The Total Length of subject device is slightly different with the prior cleared the 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 proposed S.H.A Screw and Reference device have common in all the terms in the comparison chart except the Total Length. However, this difference is not affect device's fundamental functions and safety. Therefore, it is substantial equivalent.

## Temporary Abutment

| | Subject Device | Predicate Device | Reference Device 1 | Reference Device 2 |
|---|---|---|---|---|
| **510k** | K231967 | K163634 | K203554 | K123988 |
| **Device Name (Compatible Implant System)** | **Temporary Abutment** For ARi ExCon Implant System | **Titanium Abutment** For External Hex Implants | **Temporary Abutment** For AnyOne External Implant System | **Temporary Abutment** For AnyOne Internal Implant System |
| **Manufacturer** | MegaGen Implant Co., Ltd. | Southern Implants (Pty) Ltd. | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal loading. | Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading.<br>Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved. | The AnyOne External 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 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, mm)** | 3.5, 4.0, 4.5, 5.0, 6.0 | 5.0, 6.0 | 3.9, 4.5, 4.8, 5.5 | 4.5 |
| **Post Height(mm)** | 8.0, 10.0, 12.0 | Unknown | 7.5, 10.0 | 9.5 |
| **Gingival Height(mm)** | 2.0 | 1.0, 5.0 | 1.3, 2.8 | 1.3 |
| **Angulation** | Straight | Straight | Straight | Straight |
| **Connection Interface** | External Hex | External Hex | External Hex, External Non-Hex | Internal Hex |
| **Material** | Ti-6Al-4V ELI (ASTM F136-13), POM (Delrin 100P NC010) | CPTi, Titanium alloy, Gold, CoCr | Ti-6Al-4V ELI (ASTM F136-13), | Ti-6Al-4V ELI (ASTM F136-13), POM (Delrin 100P NC010) |
| **Surface Treatment** | Machined, Anodizing | Machined | Machined | Machined |
| **Single Use** | Yes | Yes | Yes | Yes |
| **Sterilization** | Non-sterile | Sterile – irradiation | Non-sterile | Non-sterile |

**Substantial Equivalence Discussion**

1. **Similarities**

   The subject device has the same characteristic for the followings compared to the Predicate Device.
   - Indication for use, Design, Angulation, Connection Interface and Single Use.

2. **Difference**

   The subject device has the different characteristic for the followings compared to the Predicate Device.
   - Diameter

   Most diameters are within within range of predicate device and reference device. The rest of diameter(3.5mm) is slightly smaller than the diameter of reference devices. It does not cause a matter in substantial equivalence since these 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.
   - Post Height

   The Post Height of the predicate device are unknown. The post height of subject device is slightly different with reference devices. But, these 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.
   - Gingival Height

   The Gingival Height of subject device is slightly different with predicate device, but all of gingival height lie within range of predicate device.
   - Material

   The raw materials of the predicate device identified from K163634 are CPTi, Titanium alloy, Gold, CoCr, which also includes the subject

device's raw material (titanium alloy). Also, the raw materials of subject device are equivalent to the MegaGen's cleared reference device 2.

- 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.

- Sterilization

Sterilization of subject device is non-sterile. Predicate device is identified as sterilized product from K163634. Although the subject device is a non-sterile product, there are other proposed products (cover screw, healing abutment) that use the same sterilization method as the predicated device.

**3. Discussion**

The proposed Temporary Abutment and Predicate device have common in all the terms in the comparison chart except the Diameter, Post Height, Gingival Height, Material and Surface Treatment, Sterilization. These differences are not affect device's fundamental functions and safety. Also, the fatigue testing is not considered since the proposed device is straight type and temporarily used.

On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the Reference devices.

## EZ Post Abutment

| | Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| **510k** | K231967 | K163634 | K203554 |
| **Device Name (Compatible Implant System)** | **EZ Post Abutment**<br>For ARi ExCon Implant System | **Anatomic Abutment**<br>For External Hex Implants | **EZ Post Abutment**<br>For AnyOne External Implant System |
| **Manufacturer** | MegaGen Implant Co., Ltd. | Southern Implants (Pty) Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal loading. | Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved. | The AnyOne External 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, mm)** | 3.5, 4.0, 5.0, 6.0 | 3.4, 3.43, 4.05, 5.0, 6.0 | 4.0, 5.0, 6.0 |
| **Post Height(mm)** | 5.0, 6.0, 7.0, 8.0, 9.0, 10.0 | Unknown | 8.0 |
| **Gingival Height(mm)** | 2.0 | 2.0, 3.5, 5.0 | 1.0, 2.0, 3.0, 4.0 |
| **Angulation** | Straight | Straight | Straight |
| **Connection Interface** | External Hex | External Hex | External Hex, External Non-Hex |
| **Material** | Ti-6Al-4V ELI<br>(ASTM F136-13) | CPTi, Titanium alloy, Gold, CoCr | Ti-6Al-4V ELI<br>(ASTM F136-13) |
| **Surface Treatment** | Machined, Anodizing | Machined | Anodizing |
| **Single Use** | Yes | Yes | Yes |
| **Sterilization** | Non-sterile | Sterile – irradiation | Non-sterile |

**Substantial Equivalence Discussion**

**1. Similarities**

The subject device has the same characteristic for the followings compared to the prior cleared Predicate device.

- Indication for use, Design, Gingival Height, Angulation, Connection Interface and Single Use.

**2. Difference**

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

- Diameter

The Diameter of the subject device is slightly different with the Predicate device. But all of Diameter lie within range of Predicate device.

- Post Height

The Post Height of the predicate device is unknown. 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.

-Material

The raw materials of the predicate device identified from K163634 are CPTi, Titanium alloy, Gold, CoCr, which also includes the subject device's raw material (titanium alloy). Also, the raw materials of subject device are equivalent to the MegaGen's cleared reference device.

- 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.

- Sterilization

Sterilization of subject device is non-sterile. The predicate device is identified as sterilized product from K163634. Although the subject device is a non-sterile product, there are other products (cover screw, healing abutment) that use the same sterilization method as the predicated device and are equivalent to the MegaGen's cleared reference device.

**3. Discussion**

The proposed EZ Post Abutment and Predicate device have common in all the terms in the comparison chart except the Diameter, Post Height, Material and Surface Treatment, Sterilization. These differences are not affect device's fundamental functions and safety. Also, the proposed product is a straight type abutment, the fatigue test was performed as a representative of the worst case model with angle. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the Reference devices.

## Angled Abutment

| | Subject Device | Predicate Device | Reference Device 1 | Reference Device 2 |
|---|---|---|---|---|
| **510k** | K231967 | K163634 | K203554 | K110955 |
| **Device Name (Compatible Implant System)** | **Angled Abutment** For ARi ExCon Implant System | **Cosmetic Abutment** For External Hex Implants | **Angled Abutment** For AnyOne External Implant System | **Angled Abutment** For AnyRidge Internal Implant System |
| **Manufacturer** | MegaGen Implant Co., Ltd. | Southern Implants (Pty) Ltd. | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal loading. | Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved. | The AnyOne External 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 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. |
| **Design** |  |  |  |  |
| **Diameter (Ø, mm)** | 4.0, 5.0, 6.0 | 3.43, 4.05, 5.0, 6.0 | 4.0, 5.0, 6.0 | 4.0, 5.0, 6.0, 7.0 |
| **Post Height(mm)** | 7.0 | Unknown | 7.0 | 7.0 |
| **Gingival Height(mm)** | 2.0, 3.0, 4.0, 5.0 | 2.0, 2.6, 2.9, 3.0, 3.5 | 2.0, 4.0 | 1.8, 2.8, 3.8, 4.8 |
| **Angulation** | 15˚, 25˚ | 12˚, 24˚ | 15˚, 25˚ | 15°, 25° |
| **Connection Interface** | External Hex | External Hex | External Hex, External Non-Hex | Hex, Non-Hex |
| **Material** | Ti-6Al-4V ELI (ASTM F136-13) | CPTi, Titanium alloy, Gold, CoCr | Ti-6Al-4V ELI (ASTM F136-13) | Ti-6Al-4V ELI (ASTM F136-13) |
| **Surface Treatment** | Machined, Anodizing | Machined | Anodizing | Anodizing, Machined |
| **Single Use** | Yes | Yes | Yes | Yes |
| **Sterilization** | Non-sterile | Sterile – irradiation | Non-sterile | Non-sterile |

**Substantial Equivalence Discussion**

1. **Similarities**

   The subject device has the same characteristic for the followings compared to the prior cleared Predicate Device..
   - Indication for use, Design, Connection Interface and Single Use.

2. **Difference**

   The subject device has the different characteristic for the followings compared to the Predicate Device.
   - Diameter

   The Diameter of the subject device is slightly different with the prior cleared Predicate device, but all dimensions of subject device lie within range of the predicate device.
   - Post Height

   The Post Height of the predicate device is unknown. But the post height of the subject device is same as the prior cleared reference device.
   - Gingival Height

   The Gingival Height of the subject device is slightly different with the predicate device. Most dimensions are within the range of the predicate device, but some are slightly longer. However, its dimensions are almost same as MegaGen's cleared reference device 2.
   It does not cause a matter in substantial equivalence since these 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.

- Angulation

The angulation of the subject device is slightly different with the prior cleared Predicate device, but the angulation of the subject device is same as the prior cleared reference devices.

- Material

The raw materials of the predicate device identified from K163634 are CPTi, Titanium alloy, Gold, CoCr, which also includes the target device's raw material (titanium alloy). Also, the raw materials of subject device are equivalent to the MegaGen's cleared reference devices.

- 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.

-Sterilization

Sterilization of subject device is non-sterile. The Predicate device is identified as sterilized product from K163634. Although the subject device is a non-sterile product, there are other products (cover screw, healing abutment) that use the same sterilization method as the predicated device and are equivalent to the MegaGen's cleared reference device.

**3. Discussion**

The proposed Angled Abutment and Predicate device have common in all the terms in the comparison chart except the Diameter, Post Height, Gingival Height, Angulation, Material, Surface Treatment, Sterilization. The differences are explained not affecting on the substantial equivalence, but the fatigue test was performed on the subject device & Predicate device to confirm the substantial equivalence. The subject device with angled(Angled Abutment) has selected as the representative specimen in this submission according to 'ISO 14801' and 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment'. The test result supports that the subject device is substantially equivalent to the Predicate device and differences are not affecting the substantial equivalence.

## Solid Abutment

| | Subject Device | Reference Device 1 | Reference Device 2 |
|---|---|---|---|
| **510k** | K231967 | K150537 | K192347 |
| **Device Name (Compatible Implant System)** | **Solid Abutment**<br>For ARi ExCon Implant System | **Solid Abutment**<br>For MiNi Internal Implant System | **Solid Abutment**<br>For ST Internal Implant System |
| **Manufacturer** | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal loading. | The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols:<br>- The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge.- It is intended for delayed loading. | The ST Internal Implant System 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. 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, mm)** | 2.3 | 3.0, 3.5 | 4.0, 4.6, 5.0, 6.0, 7.0 |
| **Post Height(mm)** | 5.0, 7.0, 9.0 | 5.5, 7.0, 9.0 | 4.0, 5.5, 7.0 |
| **Material** | Ti-6Al-4V ELI<br>(ASTM F136-13) | Ti-6Al-4V ELI<br>(ASTM F136-13) | Ti-6Al-4V ELI<br>(ASTM F136-13) |
| **Surface Treatment** | Anodizing | Anodizing | Anodizing |
| **Single Use** | Yes | Yes | Yes |
| **Sterilization** | Non-sterile | Non-sterile | Non-sterile |

**Substantial Equivalence Discussion**

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the prior cleared Reference devices.
   - Indication for use, Design, Material, Surface Treatment, Single Use and Sterilization.
2. **Difference**
   The subject device has the different characteristic for the followings compared to the Reference devices.
   - Diameter
   The Diameter of subject device is slightly smaller than the prior cleared reference devices.
   - Post Height
   The Post Height of subject device is slightly different with the reference device, but the post height lies within range of cleared reference device 1,2. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.
3. **Discussion**
   The proposed solid Abutment and reference devices have common in Indication for use, Design, Material, Surface Treatment, Single Use, Sterilization except the Diameter and Post Height. Although there are some differences in design, these differences are not affect device's fundamental functions and safety. Also, the proposed product is a straight type abutment, the fatigue test was performed as a representative of the worst case model with angle. On the basis of the discussion above, it is concluded that the subject device is substantially equivalent to the Reference devices.

## ZrGEN Abutment

| | Subject Device | Reference Device |
|---|---|---|
| **510k** | K231967 | K220562 |
| **Device Name (Compatible Implant System)** | **ZrGEN Abutment**<br>For ARi ExCon Implant System | **ZrGEN Abutment**<br>For MegaGen's Implant systems |
| **Manufacturer** | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 chewing function in the following situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal loading.<br><br>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. | 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.<br><br>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. |
| **Design** |  |  |
| **Diameter (Ø, mm)** | 4.0, 4.5 | 3.1, 3.9, 4.0, 4.3, 4.4, 4.5, 5.0, 5.5, 6.0, 6.5 |
| **Total Length (mm)** | 6.5, 7.5, 8.0, 8.5, 9.0, 10.0, 11.0, 12.0 | 5.10, 5.50, 5.80, 7.50, 7.70, 7.90, 8.00, 8.15, 8.20, 8.35, 8.40, 8.60, 8.70, 8.85, 8.90, 9.00, 9.05, 9.20, 9.40, 9.50, 9.65, 9.70, 9.85, 9.90, 10.10, 10.35, 10.40, 10.55, 11.15, 11.35, 11.55, 11.65, 12.05, 12.55, 13.05, 13.15, 13.55, 14.05, 14.55, 15.05, 15.55, 16.55 |
| **Top-half Material** | Zirconia ISO13356 | Zirconia ISO13356 |
| **Range of Top-half Design Parameter (mm)** | Diameter: Min 8.0<br>Gingival Collar Height: Min 2.0<br>Post Height: Min 7.0 | Diameter: Min 8.0<br>Gingival Collar Height: Min 2.0<br>Post Height: Min 7.0 |
| **Angulation** | Straight | Straight |
| **Connection Interface** | Conical Connection | Conical Connection |
| **Material** | Ti-6Al-4V ELI<br>(ASTM F136-13) | Ti-6Al-4V ELI<br>(ASTM F136-13) |
| **Surface Treatment** | Machined | Machined |
| **Single Use** | Yes | Yes |
| **Sterilization** | Non-sterile | Non-sterile |

**Substantial Equivalence Discussion**

**1. Similarities**

The subject device has the same characteristic for the followings compared to the prior cleared Reference device.

- Indication for use, Design, Diameter, Top-half Material, Range of Top-half Design Parameter, Angulation, Connection Interface, Material, Surface Treatment, Single Use and Sterilization.

**2. Difference**

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

- Total Length

The Total Length of subject device is slightly different with the prior cleared the Reference device. But, The Total Length lies within range of the prior cleared Reference device.

**3. Discussion**

The proposed ZrGEN Abutment and Reference device have common in all the terms in the comparison chart except the Total Length. However, this difference is not affect device's fundamental functions and safety. Therefore, it is substantial equivalent.

## TiGEN Abutment

| | Subject Device | Reference Device |
|---|---|---|
| **510k** | K231967 | K220562 |
| **Device Name (Compatible Implant System)** | **TiGEN Abutment**<br>For ARi ExCon Implant System | **TiGEN Abutment**<br>For MegaGen's Implant systems |
| **Manufacturer** | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 chewing function in the following situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal loading.<br><br>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. | 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.<br><br>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. |
| **Design** |  |  |
| **Diameter (Ø, mm)** | 10.0, 12.0 | 10.0, 12.0 |
| **Total Length (mm)** | 26.00 | 26.00, 28.00, 28.40, 28.60, 28.70, 28.90, 29.05, 30.55 |
| **Angulation** | Up to 30° | Up to 30° |
| **Connection Interface** | Conical Connection | Conical Connection |
| **Material** | Ti-6Al-4V ELI<br>(ASTM F136-13) | Ti-6Al-4V ELI<br>(ASTM F136-13) |
| **Surface Treatment** | Anodizing and Machined | Anodizing |
| **Single Use** | Yes | Yes |
| **Sterilization** | Non-sterile | Non-sterile |
| **Substantial Equivalence Discussion** | | |

**1. Similarities**

The subject device has the same characteristic for the followings compared to the prior cleared Reference device.

- Indication for use, Design, Diameter, Angulation, Connection Interface, Material, Surface Treatment, Single Use and Sterilization.

**2. Difference & Discussion**

The proposed TiGEN Abutment and Reference device have common in all the terms in the comparison, and can be considered practically equivalent, except for the difference in the configuration of the implant used together.

## Abutment Screw

| | Subject Device | Reference Device 1 | Reference Device 2 |
|---|---|---|---|
| **510k** | K231967 | K203554 | K210161 |
| **Device Name (Compatible Implant System)** | **Abutment Screw**<br>For ARi ExCon Implant System | **Abutment Screw**<br>For AnyOne External Implant System | **Abutment Screw**<br>For AnyOne Onestage Implant System |
| **Manufacturer** | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. | MegaGen Implant Co., Ltd. |
| **Indication for use** | The ARi ExCon 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 situations and with the clinical protocols:<br>- Delayed loading<br>- Immediate loading when good primary stability is achieved and with appropriate occlusal loading. | The AnyOne External 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 AnyOne Onestage 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:<br>-Delayed loading.<br>-Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region. |
| **Design** |  |  |  |
| **Diameter (Ø, mm)** | 2.5 | 2.45, 2.5 | 2.5, 2.6 |
| **Total Length (mm)** | 5.1 | 4.8, 7.5 | 4.85, 5.5 |
| **Material** | Ti-6Al-4V ELI<br>(ASTM F136-13) | Ti-6Al-4V ELI<br>(ASTM F136-13) | Ti-6Al-4V ELI<br>(ASTM F136-13) |
| **Surface Treatment** | Machined | Machined | Machined |
| **Single Use** | Yes | Yes | Yes |
| **Sterilization** | Non-sterile | Non-sterile | Non-sterile |

**Substantial Equivalence Discussion**

1. **Similarities**
   The subject device has the same characteristic for the followings compared to the prior cleared reference device 1.
   - Indication for use, Design, Diameter, Material, Surface Treatment, Single Use and Sterilization.
2. **Difference**
   The subject device has the different characteristic for the followings compared to the reference device 1.
   - Total Length
     The Total Length of subject device is slightly different with the prior cleared reference device 1. The Total Length of subject device is slightly different with Reference device 1, but the dimension of subject device lies within range Reference devices. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.
3. **Discussion**
   The proposed Abutment Screw and reference device 1 have common in all the items except the Total Length. The Total Length difference is explained not affecting on the substantial equivalence.

## 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. The additional biocompatibility testing is not required on the ARi ExCon Implant system since ARi ExCon Implant system has same material composition, manufacturing process and patient contacting parts as the previously cleared device, XPEED AnyRidge Internal System (K122231), BLUEDIAMOND Implant System (K182448) and AnyRidge Internal Implant System (K110955).

**Pyrogen and Endotoxin Test**

The subject device will not be labeled as "non-pyrogenic", and the endotoxin testing will be conducted on every batch for the subject device with the testing limit of below 0.5 EU/mL in accordance with the USP 39 <85>.

**Sterilization validation and Shelf life**

The ARi ExCon Implant, Cover Screw, Healing Abutment, Scan Healing Abutment and S.H.A Screw are supplied in sterile state. Sterilization validating testing has been performed in accordance with ISO 11137 to verify the sterility assurance level ($10^{-6}$). The tests to validate the shelf life of the device through the proposed shelf life were conducted using the accelerated aging method in accordance to ASTM F1980 and the test results validated 5 years shelf life. The subject device is evaluated with previous device which was evaluated under the previous 510(k) submission, K122231.
Also, the following guidance documents were referred to:

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

The Temporary Abutment, EZ Post Abutment, Angled Abutment, Solid Abutment, ZrGEN Abutmemt, TiGEN Abutment and Abutment Screw are supplied in non-sterile state. Sterilization validating testing for steam sterilization by the user has been performed in accordance with ISO 17665-1 and ISO 17665-2 to verify the sterility assurance level ($10^{-6}$). Validation Testing was conducted on a worst-case test article from our previously cleared device, K220562.

**Modified Surface Treatment**

The surface treatment evaluation has been performed in accordance with 'Section 11 of Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments – Guidance for Industry and FDA Staff".
The ARi ExCon Implant has same surface and manufacturing process with the previously our cleared devices of XPEED AnyRidge Internal System (K122231) for the surface treatment of S.L.A.
The Cover Screw, Healing Abutment, Scan Healing Abutment, S.H.A Screw, Temporary Abutment, EZ Post Abutment, Angled Abutment, Solid Abutment, TiGEN Abutment and ZrGEN Abutment have the same anodized surface treatment and manufacturing process as our previously cleared device, MiNi Internal Implant System (K150537), AnyOne External Implant System (K203554) and BLUEDIAMOND IMPLANT System (K182448).

**Performance test**

The following bench tests have been performed in accordance with "ISO 14801" and "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.

▪ Fatigue test

**MR Compatibility**

The MR compatibility was performed to access the risk of exposing patients who have implantable medical devices according to FDA's guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment".

An assessment was made to demonstrate that the subject devices do not configure a new worst case and can be represented by the previously conducted studies reviewed for reference devices obtained the status of MR Conditional per K230618. Therefore, the subject devices are MR conditional devices and a patient treated with the subject devices can be safely scanned observing the parameters previously established per reference devices.

## 9. Conclusion

Based on the information provided in this premarket notification, We, MegaGen Implant Co., Ltd. conclude that the ARi ExCon Implant System is substantially equivalent to the predicate device as here.