March 9, 2024

Implant Solutions PTY LTD (aka Osteon Medical)
℅ Farah Rahman
QA/RA Manager
759-767 Springvale Road
Mulgrave, Victoria 3170
AUSTRALIA

Re: K233083
Trade/Device Name: Osteon Precision Milled Suprastructure
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 30, 2024
Received: February 5, 2024

Dear Farah Rahman:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233083

Device Name
Osteon Precision Milled Suprastructure

Indications for Use *(Describe)*
The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) abutments.

The Osteon Milled Suprastructure is indicated for compatibility with the following abutment systems:

- Astra Tech Implant System® Multi Base Abutment EV, 4.8mm, max 30°
- BioHorizons Multi Unit Abutment, 4.8mm, max 30°
  - CONELOG® Implant System
- Biomet 3i Multi Unit Abutments, 4.8mm, max 30°
  - TSX™ Implants
  - Tapered Screw-Vent Implant
- DESS Dental Multi Unit Abutments, 3.4-5.7 mm, 0°
  - 3i OSSEOTITE®
  - Astra Tech OsseoSpeed™
  - Neodent Grand Morse
  - NobelReplace® Trilobe
  - NobelReplace® Conical
  - Nobel Brånemark System®
  - Straumann BLX Implants
- DESS Dental Multi Unit Abutments, Angled, 3.4-6.5 mm, max 30°
  - NobelActive® NobelParallel Conical
  - Straumann® Bone Level
  - Zimmer Screw Vent® and Tapered Screw-Vent®
- Dentium SuperLine® Abutments, 4.5-5.5 mm, max30°
- Genesis ACTIVE™ Multi-Unit Abutments, 4.8mm, max 30°
- Implant Direct GPS® Angled Abutment, 5.0mm, max 30°
- KDG Abutments, 4.8mm, max 30°
- Keystone Multi Unit Abutment, 4.8mm, 0°
- Medentika Multi Unit Abutments, 4.8mm, max 30°
  - EV Series – Dentsply® Implants Astratech Osseospeed®
  - F Series – Nobel Biocare NobelActive® – NobelReplace® Conical
  - H Series – Biomet 3i Certain®
  - L Series – Straumann Bone Level
  - N Series – Straumann Soft tissue Level
  - R Series – Zimmer Dental Tapered Screwvent®
- Medentika Multi Unit Abutments, 4.8mm, 0°
  - E Series – Nobel Biocare Replace™ Select
  - I Series – Biomet 3i Osseotite®
  - K Series – Nobel Biocare™ Branemark
  - S Series – Astra Tech OsseoSpeed™
  - T Series – Dentsply Friadent® Frialit/Xive®
- MegaGen Multi Unit Abutments, 4.8mm, max 30°

    - Xpeed® AnyRidge® Internal Implant System
    - AnyOne® Internal Implant System
    - AnyRidge® Octa 1 Implant System
    - AnyOne® External Implant System
    - AnyRidge® Octa 1 Implant System
    - AnyOne® Internal Implant System
    - Rescue Internal Implant System
- MIS Multi-unit Abutments, 4.8mm
    - C1 Conical Connection Implant System, max 30°
    - V3 Conical Connection Implant System, max 30°
    - Internal Hex Implant System, max 30°
    - Conical Connection, max 30°
- Neodent GM Mini Conical Abutment, 4.8 mm, max 30°
- Nobel Biocare™ Brånemark Multi Unit Abutment, 4.8 mm, max 17°
- Nobel Biocare™ Multi Unit Abutment Plus, 4.8 mm, max 30°
- Nobel Biocare™ Multi Unit Abutment, 4.8 mm, max 30°
- Nobel Biocare™ Multi Unit Abutments for Straumann and Astra Tech System, 4.8 mm, max 30°
- Nobel Biocare™ Multi Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems, 4.8 mm, max 30°
- Nobel Biocare Xeal Abutments, 4.8 mm, max 30°
- OSSTEM Multi Unit Abutment, 4.8mm, max 30°
    - SS SA Fixture Implants
    - SA Implant System
    - ET US SSS Prosthetic System
- Paltop Multi Unit Abutment, 5.0 mm, max 17°
- Southern Compact Conical Abutments, 4.8 mm
    - MAX Implant System, 0°
    - Provata Implant System, max 30°
    - Deep Conical (DC) Implants, 0°
    - Piccolo Implants, 0°
    - External Hex Implants, max 30°
- Straumann® BLX Screw Retained Abutment, 4.6 mm, max 30°
- Straumann® Screw Retained Abutment, 4.6 mm, max 30°
- Zimmer Angled Tapered Abutments, 4.5 mm, max 30°

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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510(k) Summary

K233083

Implant Solutions PTY LTD (aka Osteon Medical)

Osteon Precision Milled Suprastructure

March 08, 2024

ADMINISTRATIVE INFORMATION

Manufacturer	Implant Solutions PTY LTD (aka Osteon Medical) 759-767 Springvale Road Mulgrave, Victoria 3170, Australia Telephone: +61 392-640-111
Official Contact	Farah Rahman, QARA Manager

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	Osteon Precision Milled Suprastructure
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Office	Office of Health Technology 1 (OHT 1: Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Health Technology 1 B (Dental and ENT Devices)

PREDICATE DEVICE INFORMATION

Primary Predicate Device:

- K221019, Osteon Precision Milled Suprastructure, Implant Solutions PTY LTD (aka Osteon Medical)

Reference Devices for OEM Compatibilities:

- K212676, Osteon Precision Milled Suprastructure, Implant Solutions Pty Ltd (aka Osteon Medical)
- K221381, KDG Abutments, Keystone Dental Inc.
- K223814, Genesis ACTIVE Implant System, Keystone Dental Inc.
- K203252, Multi-unit Abutments for CONELOG®, BioHorizons Implant Systems, Inc.
- K092341, Low Profile Abutments – Internal and External Connection, Biomet 3I, Inc.
- K203808, Multi-unit Abutment, Multi-unit Angled Abutment, MegaGen Implant Co., Ltd.
- K203554, AnyOne® External Implant System, MegaGen Implant Co., Ltd.

- K063216, Rescue Internal Dental Implant System, MegaGen Implant Co., Ltd.
- K221684, OSSTEM Abutment System, Osstem Implant Co., Ltd.
- K163557, SS SA Fixture, Osstem Implant Co., Ltd.
- K161689, OSSTEM Implant System – Abutment, Osstem Implant Co., Ltd
- K161103, US SA Implant System, Osstem Implant Co., Ltd.
- K160670, ET US SS Prosthetic system, Osstem Implant Co., Ltd.
- K123755, Multi Angled Abutment, Osstem Implant Co., Ltd.
- K191123, Multi-unit Abutments, Medentika GmbH
- K142167, Medentika Abutment System, Medentika GmbH

INDICATIONS FOR USE STATEMENT

The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) abutments.

The Osteon Milled Suprastructure is indicated for compatibility with the following abutment systems:

- Astra Tech Implant System® Multi Base Abutment EV, 4.8mm, max 30°
- BioHorizons Multi Unit Abutment, 4.8mm, max 30°
    - CONELOG® Implant System
- Biomet 3i Multi Unit Abutments, 4.8mm, max 30°
    - TSX™ Implants
    - Tapered Screw-Vent Implant
- DESS Dental Multi Unit Abutments, 3.4-5.7 mm, 0°
    - 3i OSSEOTITE®
    - Astra Tech OsseoSpeed™
    - Neodent Grand Morse
    - NobelReplace® Trilobe
    - NobelReplace® Conical
    - Nobel Brånemark System®
    - Straumann BLX Implants
- DESS Dental Multi Unit Abutments, Angled, 3.4-6.5 mm, max 30°
    - NobelActive® NobelParallel Conical
    - Straumann® Bone Level
    - Zimmer Screw Vent® and Tapered Screw-Vent®
- Dentium SuperLine® Abutments, 4.5-5.5 mm, max30°
- GENESIS ACTIVE™ Multi-Unit Abutments, 4.8mm, max 30°
- Implant Direct GPS® Angled Abutment, 5.0mm, max 30°
- KDG Abutments, 4.8mm, max 30°
- Keystone Multi Unit Abutment, 4.8mm, 0°
- Medentika Multi Unit Abutments, 4.8mm, max 30°
    - EV Series – Dentsply® Implants Astratech Osseospeed®
    - F Series – Nobel Biocare NobelActive® – NobelReplace® Conical
    - H Series – Biomet 3i Certain®
    - L Series – Straumann Bone Level

    - N Series – Straumann Soft tissue Level
    - R Series – Zimmer Dental Tapered Screwvent®
- Medentika Multi Unit Abutments, 4.8mm, 0°
    - E Series – Nobel Biocare Replace™ Select
    - I Series – Biomet 3i Osseotite®
    - K Series – Nobel Biocare™ Branemark
    - S Series – Astra Tech OsseoSpeed™
    - T Series – Dentsply Friadent® Frialit/Xive®
- MegaGen Multi Unit Abutments, 4.8mm, max 30°
    - Xpeed® AnyRidge® Internal Implant System
    - AnyOne® Internal Implant System
    - AnyRidge® Octa 1 Implant System
    - AnyOne® External Implant System
    - AnyRidge® Octa 1 Implant System
    - AnyOne® Internal Implant System
    - Rescue Internal Implant System
- MIS Multi-unit Abutments, 4.8mm
    - C1 Conical Connection Implant System, max 30°
    - V3 Conical Connection Implant System, max 30°
    - Internal Hex Implant System, max 30°
    - Conical Connection, max 30°
- Neodent GM Mini Conical Abutment, 4.8 mm, max 30°
- Nobel Biocare™ Brånemark Multi Unit Abutment, 4.8 mm, max 17°
- Nobel Biocare™ Multi Unit Abutment Plus, 4.8 mm, max 30°
- Nobel Biocare™ Multi Unit Abutment, 4.8 mm, max 30°
- Nobel Biocare™ Multi Unit Abutments for Straumann and Astra Tech System, 4.8 mm, max 30°
- Nobel Biocare™ Multi Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems, 4.8 mm, max 30°
- Nobel Biocare Xeal Abutments, 4.8 mm, max 30°
- OSSTEM Multi Unit Abutment, 4.8mm, max 30°
    - SS SA Fixture Implants
    - SA Implant System
    - ET US SSS Prosthetic System
- Paltop Multi Unit Abutment, 5.0 mm, max 17°
- Southern Compact Conical Abutments, 4.8 mm
    - MAX Implant System, 0°
    - Provata Implant System, max 30°
    - Deep Conical (DC) Implants, 0°
    - Piccolo Implants, 0°
    - External Hex Implants, max 30°
- Straumann® BLX Screw Retained Abutment, 4.6 mm, max 30°
- Straumann® Screw Retained Abutment, 4.6 mm, max 30°
- Zimmer Angled Tapered Abutments, 4.5 mm, max 30°

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the Osteon Precision Milled Suprastructure cleared under K221019, K2121019, K221381 and K223814 to add additional OEM compatibility to BioHorizons Abutments, Biomet 3i Abutments, MegaGen Abutments, OSSTEM Abutments, and Medentika Abutments. Three (3) additional Type B Nexus Fixed Bars have been designed to accommodate additional fixed dental prosthesis types (Nexus Bridge, Micro Nexus, and Nexus Wraparound). The Micro Nexus Bar can be utilized when up to half of the arch is considered for a restoration, while the Nexus Hybrid, Nexus Bridge, and Nexus Wraparound are utilized for full arched fixed restorations and selection of the bar type is made based on aesthetic requirements of the patient.

The Osteon Precision Milled Suprastructures (also referred to as superstructures) are metallic dental restorative devices that are intended to be attached by screw retention to dental implant abutments to aid in the treatment of partial and totally edentulous patients for the purpose of restoring chewing function. These suprastructures attach to dental implant abutments using the prosthetic screws from the original equipment manufacturers (OEM) and are used to support the final multi-unit restoration.

The Osteon Precision Milled Suprastructure is designed for an individual patient from scans of the patient's dental impression. The suprastructure is manufactured with the aid of Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) technology. All CAD/CAM fabrication is performed by Osteon Medical.

Osteon Precision Milled Suprastructures facilitate the attachment of both removable and fixed dental prosthesis and hence are categorized as Type A and Type B.

- Type A: Intended to act as a supporting structure to facilitate the attachment of a removable dental prosthesis and include Primary Bar and Nexus Removable Bar.
- Type B: Intended to act as a supporting structure to facilitate the attachment of a fixed dental prosthesis and include Melbourne Bar and Nexus Fixed Bar (including Nexus Hybrid, Nexus Bridge, Micro Nexus, and Nexus Wraparound).

The table below presents the design specifications for two categories of suprastructures:

Description	**Type A (For Removable Prosthesis)**		**Type B (For Fixed Prosthesis)**	
	Minimum	Maximum	Minimum	Maximum
Total Cylinders	2	10	2	10
Suprastructure Span Between Cylinders (mm)	1	30	1	30
Suprastructure Height (mm)	3	12	3*	22
Suprastructure Width (mm)	3.4	12	3.4**	12
Distal Cantilever Section (mm)***	0	15	0	15
Cylinder Height (mm)	0	4.6	0	4.6
Cylinder Diameter (mm)	4.5	8	4.5	8

*The Minimum Suprastructure Height for the Micro Nexus Bar is 2.5 mm. This is where the cut outs are present. Cutouts are optional.

**The Minimum Suprastructure Width for the Micro Nexus Bar is 2.5 mm. This is where the cut outs are present. Cutouts are optional.

***Distal Cantilever Section is not applicable for Micro Nexus Bar as this bar could be designed to fit anywhere within the arch.

MATERIAL COMPOSITION

The Osteon Precision Milled Suprastructure is manufactured from titanium alloy conforming to the requirements of ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*. This material is identical to that of the primary predicate device K221019.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: biocompatibility according to ISO 10993-5 and ISO 10993-12 leveraged from K212676; sterilization validation according to ANSI/AAMI/ISO 17665-1, ANSI/AAMI/ISO 17665-2 and ANSI/AAMI/ISO 14937 and reverse engineering analysis of OEM abutments and OEM abutment screws to confirm compatibility. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICE

The Subject device is substantially equivalent in indications and design principles to the primary predicate device listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the Subject device and the Primary Predicate device K221019 and Reference devices K212676, K221381 and K223814.

The Subject device is substantially equivalent in intended use to the Primary Predicate device cleared in K221019 and Reference Devices K212676, K221381 and K223814. The Indications for Use Statement (IFUS) for the Subject device is substantially equivalent to that of the Primary Predicate K221019, except for the list of compatible OEM implants.

The Subject device is identical in design, materials, and technological characteristics to the corresponding Primary Predicate device K221019 and Reference devices K212676, K221381 and K223814. There have been no changes to the previously cleared bars, and they remain the same as the Primary Predicate K221019. New bar cylinders (mating components) have been designed to accommodate the new compatible abutments that, other than the compatibilities, are identical to the bar cylinders that were cleared in the Primary Predicate K221019. Three additional Type B Fixed Prosthesis Bars are within this submission, including the Nexus Bridge, Micro Nexus, and Nexus Wraparound. These bars are similar in design to the Primary Predicate K221019, with the use of the bar cylinders to create the custom bar design for a specific patient. Fatigue testing was not performed since the Subject devices are abutment-borne and are not intended to compensate for angulation in excess of the maximum angulation of OEM angled abutments in each Reference device clearance, as outlined in the Indications for Use Statement.

The Subject device is to be sterilized by the end-user, highly similar to primary predicate device K221019 and Reference devices K212676, K221381 and K223814.

The Subject device is to be manufactured from the same materials and in the same facilities using the same manufacturing processes as used for the Osteon Precision Milled Suprastructure previously cleared in K221019. Therefore, no new biocompatibility testing has been performed, as the Subject device is substantially equivalent to the predicate devices in K221019 and the Reference devices in K212676, K221381 and K223814 with regard to materials and processing.

CONCLUSION

The Subject device and the primary predicate device have the same intended use, have similar technological characteristics, and are made of the same materials. The Subject device and the primary predicate encompass the same range of physical dimensions, are packaged in same materials, and are to be sterilized using highly similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Table of Substantial Equivalence – Technological Characteristics

Characteristic	Subject Device: Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)	Primary Predicate Device: Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)	Reference Device: Osteon Precision Milled Suprastructure, K212676 Implant Solutions PTY LTD (aka Osteon Medical)	Reference Device: KDG Abutments, K221381, Keystone Dental Inc.	Reference Device: Genesis ACTIVE Implant System, K223814, Keystone Dental Inc.
Indications	The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) abutments. The Osteon Milled Suprastructure is indicated for compatibility with the following abutment systems: • Astra Tech Implant System® Multi Base Abutment EV, 4.8mm, max 30° • BioHorizons Multi Unit Abutment, 4.8mm, max 30° • CONELOG® Implant System • Biomet 3i Multi Unit Abutments, 4.8mm, max 30° • TSX™ Implants • Tapered Screw-Vent Implant • DESS Dental Multi Unit Abutments, 3.4-5.7 mm, 0° • 3i OSSEOTITE® • Astra Tech OsseoSpeed™ • Neodent Grand Morse • NobelReplace® Trilobe • NobelReplace® Conical • Nobel Brånemark System® • Straumann BLX Implants • DESS Dental Multi Unit Abutments, Angled, 3.4-6.5 mm, max 30° • NobelActive® NobelParallel Conical • Straumann® Bone Level	The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) abutments. The Osteon Milled Suprastructure is indicated for compatibility with the following abutment systems: • Astra Tech Implant System® Multi Base Abutment EV, 4.8 mm, max 30° • DESS Dental Multi Unit Abutments, 3.4-5.7 mm, 0° • 3i OSSEOTITE® • Astra Tech OsseoSpeed™ • Neodent Grand Morse • NobelReplace® Conical • NobelReplace® Trilobe • Nobel Brånemark System® • Straumann BLX Implants • DESS Dental Multi Unit Abutments, Angled, 3.4-6.5 mm, max 30° • NobelActive® NobelParallel Conical • Straumann® Bone Level • Zimmer Screw Vent® and Tapered Screw-Vent® • Dentium SuperLine® Abutments, 4.5-5.5 mm, max 30°	The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) abutments. The Osteon Milled Suprastructure is indicated for compatibility with the following abutment systems: • Astra Tech Implant System® Multi Base Abutment EV, 4.8 mm, max 30° • Dentium SuperLine® Abutments, 4.5-5.5 mm, max 30° • Keystone Multi Unit Abutment, 4.8 mm, 0° • Implant Direct GPS® Angled Abutment, 5.0 mm, max 30° • MIS Multi-unit Abutments, 4.8 mm • C1 Conical Connection Implant System, max 30° • V3 Conical Connection Implant System, max 30° • Internal Hex Implant System, max 30° • Conical Connection, max 30° • Neodent GM Mini Conical Abutment, 4.8 mm, max 30° • Nobel Biocare Multi Unit Abutment Plus, 4.8 mm, max	KDG Abutments are pre-manufactured prosthetic components for direct connection to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. The KDG-Osteon Precision Milled Suprastructure is indicated for attachment to KDG Abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The KDG-Osteon Precision Milled Suprastructure is intended for attachment to a minimum of two (2) abutments.	The Genesis ACTIVE Implant System is intended for use in single-stage or two-stage surgical procedures for replacing single or multiple missing teeth in partially or fully edentulous mandibles and maxillae. The Genesis ACTIVE Implant System supports single or multiple-unit restorations to re-establish patient chewing function and esthetics. Genesis ACTIVE implants are intended for placement following natural tooth loss or for immediate placement into an extraction socket. Immediate function may be achieved when good primary stability is established, and appropriate occlusal loading is applied. All digitally designed custom abutments for use with Genesis ACTIVE Implant System implants are to be sent to a Keystone Dental validated milling center for manufacture. The KDG-Osteon Precision Milled Suprastructure is indicated for attachment to the Genesis ACTIVE Multi-Unit abutments in the treatment of

Characteristic	Subject Device: Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)	Primary Predicate Device: Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)	Reference Device: Osteon Precision Milled Suprastructure, K212676 Implant Solutions PTY LTD (aka Osteon Medical)	Reference Device: KDG Abutments, K221381, Keystone Dental Inc.	Reference Device: Genesis ACTIVE Implant System, K223814, Keystone Dental Inc.
	• Zimmer Screw Vent® and Tapered Screw-Vent® • Dentium SuperLine® Abutments, 4.5-5.5 mm, max30° • GENESIS ACTIVE™ Multi-Unit Abutments, 4.8mm, max 30° • Implant Direct GPS® Angled Abutment, 5.0mm, max 30° • KDG Abutments, 4.8mm, max 30° • Keystone Multi Unit Abutment, 4.8mm, 0° • Medentika Multi Unit Abutments, 4.8mm, max 30° • EV Series – Dentsply® Implants Astratech Osseospeed® • F Series – Nobel Biocare NobelActive® – NobelReplace® Conical • H Series – Biomet 3i Certain® • L Series – Straumann Bone Level • N Series – Straumann Soft tissue Level • R Series – Zimmer Dental Tapered Screwvent® • Medentika Multi Unit Abutments, 4.8mm, 0° • E Series – Nobel Biocare Replace™ Select • I Series – Biomet 3i Osseotite® • K Series – Nobel Biocare™ Branemark • S Series – Astra Tech OsseoSpeed™ • T Series – Dentsply Friadent® Frialit/Xive®	• Keystone Multi Unit Abutment, 4.8 mm, 0° • Implant Direct GPS® Angled Abutment, 5.0 mm, max 30° • MIS Multi-unit Abutments, 4.8 mm • C1 Conical Connection Implant System, max 30° • V3 Conical Connection Implant System, max 30° • Internal Hex Implant System, max 30° • Conical Connection, max 30° • Neodent GM Mini Conical Abutment, 4.8 mm, max 30° • Nobel Biocare Brånemark Multi Unit Abutment, 4.8 mm, max 30° • Nobel Biocare Multi Unit Abutment Plus, 4.8 mm, max 30° • Nobel Biocare Multi Unit Abutment, 4.8 mm, max 30° • Nobel Biocare Multi Unit Abutments for Straumann and Astra Tech System, 4.8mm, max 30° • Nobel Biocare Multi Unit Abutments for Astra Tech, Camlog and Ankylos Implant Systems, 4.8 mm, max 30° • Nobel Biocare Xeal Abutments, 4.8 mm, max 30° • Paltop Multi Unit Abutment, 5.0 mm, max 17° • Southern Compact Conical Abutments, 4.8 mm • MAX Implant System, 0° • Provata Implant System, max 30° • Deep Conical (DC) Implants,	30° • Nobel Biocare Multi Unit Abutment, 4.8 mm, max 30° • Nobel Biocare Xeal Abutments, 4.8 mm, max 30° • Paltop Multi Unit Abutment, 5.0 mm, max 17° • Southern Compact Conical Abutments, 4.8 mm • MAX Implant System, 0° • Provata Implant System, max 30° • Deep Conical (DC) Implants, 0° • Piccolo Implants, 0° • External Hex Implants, max 30° Zimmer Angled Tapered Abutments, 4.5 mm, max 30°		partially or fully edentulous jaws for the purpose of restoring chewing function. The KDGOsteon Precision Milled Suprastructure is intended for attachment to a minimum of two (2) abutments.

Characteristic	Subject Device: Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)	Primary Predicate Device: Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)	Reference Device: Osteon Precision Milled Suprastructure, K212676 Implant Solutions PTY LTD (aka Osteon Medical)	Reference Device: KDG Abutments, K221381, Keystone Dental Inc.	Reference Device: Genesis ACTIVE Implant System, K223814, Keystone Dental Inc.

	• MegaGen Multi Unit Abutments, 4.8mm, max 30°
	  • Xpeed® AnyRidge® Internal Implant System
	  • AnyOne® Internal Implant System
	  • AnyRidge® Octa 1 Implant System
	  • AnyOne® External Implant System
	  • AnyRidge® Octa 1 Implant System
	  • AnyOne® Internal Implant System
	  • Rescue Internal Implant System
	• MIS Multi-unit Abutments, 4.8mm
	  • C1 Conical Connection Implant System, max 30°
	  • V3 Conical Connection Implant System, max 30°
	  • Internal Hex Implant System, max 30°
	  • Conical Connection, max 30°
	• Neodent GM Mini Conical Abutment, 4.8 mm, max 30°
	• Nobel Biocare™ Brånemark Multi Unit Abutment, 4.8 mm, max 17°
	• Nobel Biocare™ Multi Unit Abutment Plus, 4.8 mm, max 30°
	• Nobel Biocare™ Multi Unit Abutment, 4.8 mm, max 30°
	• Nobel Biocare™ Multi Unit Abutments for Straumann and Astra Tech System, 4.8 mm, max 30°
	• Nobel Biocare™ Multi Unit Abutments for Astra Tech,
		0°
		  • Piccolo Implants, 0°
		  • External Hex Implants, max 30°
		• Straumann® BLX Screw Retained Abutment, 4.6 mm, max 30°
		• Straumann® Screw Retained Abutment, 4.6 mm, max 30°
		• Zimmer Angled Tapered Abutments, 4.5 mm, max 30°			

Characteristic	Subject Device: Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)	Primary Predicate Device: Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)	Reference Device: Osteon Precision Milled Suprastructure, K212676 Implant Solutions PTY LTD (aka Osteon Medical)	Reference Device: KDG Abutments, K221381, Keystone Dental Inc.	Reference Device: Genesis ACTIVE Implant System, K223814, Keystone Dental Inc.

	Camlog and Ankylos Implant Systems, 4.8 mm, max 30°
	• Nobel Biocare Xeal Abutments, 4.8 mm, max 30°
	• OSSTEM Multi Unit Abutment, 4.8mm, max 30°
	  • SS SA Fixture Implants
	  • SA Implant System
	  • ET US SSS Prosthetic System
	• Paltop Multi Unit Abutment, 5.0 mm, max 17°
	• Southern Compact Conical Abutments, 4.8 mm
	  • MAX Implant System, 0°
	  • Provata Implant System, max 30°
	  • Deep Conical (DC) Implants, 0°
	  • Piccolo Implants, 0°
	  • External Hex Implants, max 30°
	• Straumann® BLX Screw Retained Abutment, 4.6 mm, max 30°
	• Straumann® Screw Retained Abutment, 4.6 mm, max 30°
	• Zimmer Angled Tapered Abutments, 4.5 mm, max 30°				

Device Material	Titanium alloy Ti-6Al- 4V	Titanium alloy Ti-6Al- 4V	Titanium alloy Ti-6Al- 4V	Grade 23 Titanium Alloy, No modified surface	Titanium alloy Ti-6Al- 4V
Design/Technology	CAD/CAM milling from single milling blanks.	CAD/CAM milling from single milling blanks.	CAD/CAM milling from single milling blanks.	CAD/CAM milling	CAD/CAM milling
Design/Construction	Patient specific/ machined	Patient specific/ machined	Patient specific/ machined	Patient specific/ machined	Patient specific/ machined
Sterility	Supplied Nonsterile	Supplied Nonsterile	Supplied Nonsterile	Supplied Nonsterile	Supplied Nonsterile
Prescription/OTC	Prescription only	Prescription only	Prescription only	Prescription only	Prescription only
Recommended Cleaning and Maintenance	Proper oral hygiene	Proper oral hygiene	Proper oral hygiene	Proper oral hygiene	Proper oral hygiene

Table of Substantial Equivalence – Design Specifications

Characteristic	Subject Device: Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)		Primary Predicate Device: Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)		Reference Device: Osteon Precision Milled Suprastructure, K212676 Implant Solutions PTY LTD (aka Osteon Medical)		Reference Device: KDG Abutments, K221381, Keystone Dental Inc.		Reference Device: Genesis ACTIVE Implant System, K223814, Keystone Dental Inc.	
Design Specifications	**Type A**	**Type B**	**Type A**	**Type A**	**Type A**	**Type A**	**Type A**	**Type B**	**Type A**	**Type B**
Total Cylinders	2-10	2-10	2-10	2-10	2-10	2-10	2-10	2-10	2-10	2-10
Suprastructure Span Between Cylinders (mm)	1-30 mm	1-30 mm	1-30 mm	1-30 mm	1-30 mm	1-30 mm	1-30 mm	1-30 mm	1-30 mm	1-30 mm
Suprastructure Height (mm)	3-12 mm	3*-22 mm	3-12 mm	3-12 mm	3-12 mm	3-12 mm	3-12 mm	3-22 mm	3-12 mm	3-22 mm
Suprastructure Width (mm)	3.4-12 mm	3.4**-12 mm	3.4-12 mm	3.4-12 mm	3.4-12 mm	3.4-12 mm	3.4-12 mm	3.4-12 mm	3.4-12 mm	3.4-12 mm
Distal Cantilever Section (mm)***	0-15 mm	0-15 mm	0-15 mm	0-15 mm	0-15 mm	0-15 mm	0-15 mm	0-15 mm	0-15 mm	0-15 mm
Cylinder Height (mm)	0-4.6 mm	0-4.6 mm	0-4.6 mm	0-4.6 mm	0-4.6 mm	0-4.6 mm	0-4.6 mm	0-4.6 mm	0-4.6 mm	0-4.6 mm
Cylinder Diameter (mm)	4.5-8 mm	4.5-8 mm	4.5-8 mm	4.5-8 mm	4.5-8 mm	4.5-8 mm	4.5-8 mm	4.5-8 mm	4.5-8 mm	4.5-8 mm

*The Minimum Suprastructure Height for the Micro Nexus Bar is 2.5 mm. This is where the cut outs are present. Cutouts are optional.

**The Minimum Suprastructure Width for the Micro Nexus Bar is 2.5 mm. This is where the cut outs are present. Cutouts are optional.

***Distal Cantilever Section is not applicable for Micro Nexus Bar as this bar could be designed to fit anywhere within the arch.