Implant Solutions PTY LTD (aka Osteon Medical)
℅ Melissa Burbage
Senior Regulatory Specialist
PaxMed International, LLC
12264 EL Camino Real, Suite 400
San Diego, California 92130

Re: K221019
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: April 5, 2022
Received: April 6, 2022

Dear Melissa Burbage:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Andrew 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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221019

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, 4.8 mm, max 30°
- 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, 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 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°
- Paltop Multi Unit Abutment, 5.0 mm, 0°
- 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

K221019

Implant Solutions PTY LTD (aka Osteon Medical)

Osteon Precision Milled Suprastructure

June 30, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Implant Solutions PTY LTD (aka Osteon Medical) 759-767 Springvale Road Mulgrave, Victoria 3170, Australia Telephone: +61 408-583-222
Official Contact	Ms. Andrea Del Ciotto, Head of Regulatory Compliance
Representative/Consultant	Melissa Burbage Kevin A. Thomas, PhD; Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: mburbage@paxmed.com kthomas@paxmed.com; flarson@paxmed.com

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

- K212676, Osteon Precision Milled Suprastructure, Implant Solutions PTY LTD (aka Osteon Medical)

Reference Device for OEM Compatibilities

- K170588, DESS Dental Smart Solutions, Terrats Medical SL
- K191986, DESS Dental Smart Solutions, Terrats Medical SL
- K212628, DESS Dental Smart Solutions, Terrats Medical SL
- K211109, N1™ TiUltra™ TCC Implant System, Nobel Biocare Services AG

- K093643, Multi-Unit Abutments for Straumnann and AstraTech Implant Systems, Nobel Biocare Services USA LLC
- K061477, Multi-Unit Abutments for AstraTech, Camlog, and Ankylos Implant Systems, Nobel Biocare Services USA LLC
- K961736, 17° Angulated Abutment, Nobel Biocare Services USA LLC
- K181703, Straumann® BLX Line Extension - Implants, SRAs and Anatomic Abutments, Straumann USA, LLC
- K171757, Straumann® Screw Retained Abutments, Straumann USA, LLC
- K192401, Straumann® Screw-Retained Abutments, Straumann USA, LLC

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, 4.8 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°
- 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 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°
- 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 K212676 to add additional OEM compatibility to DESS Abutments, Nobel Biocare Abutments, and Straumann Abutments.

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 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 fixed dental prosthesis and include Melbourne Bar and Nexus Fixed Bar

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

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 K212676.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation according to ANSI/AAMI/ISO 17665-1 and ISO 17665-2, leveraged from K212676; biocompatibility

according to ISO 10993-5 and ISO 10993-12 leveraged from K212676; and reverse engineering analysis of OEM abutments to confirm compatibility. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

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.

The subject device is substantially equivalent in intended use to the primary predicate device cleared in K212676. The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K212676, 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 K212676. There have been no changes to the bars, and they remain the same as the primary predicate K212676. 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 K212676. 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, the same as primary predicate device K212676.

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 K212676. Therefore, no new biocompatibility testing has been performed, as the subject device is substantially equivalent to the predicate devices in K212676 with regard to materials and processing.

Table of Substantial Equivalence – Technological Characteristics

	Subject Device	Primary Predicate Device
	Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)	K212676 Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)
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, 4.8 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° • 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 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, 4.8mm, 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, 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°	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 Precision Milled Suprastructures are indicated for compatibility with the following abutment systems: ● Nobel Biocare Multi Unit Abutment Plus, 4.8mm, max 30° ● Nobel Biocare Xeal Abutments, 4.8mm, max 30° ● Nobel Biocare Multi Unit Abutment, 4.8mm, max 30° ● MIS Multi-unit Abutments, 4.8mm o C1 Conical Connection Implant System, max 30° o V3 Conical Connection Implant System, max 30° o Internal Hex Implant System, max 30° o Conical Connection, max 30° ● Southern Compact Conical Abutments, 4.8mm o MAX Implant System, 0° o Provata Implant System, max 30° o Deep Conical (DC) Implants, 0° o Piccolo Implants, 0° o External Hex Implants, max 30° ● Astra Tech Implant System® Multi Base Abutment EV, 4.8mm, max 30° ● Keystone Multi Unit Abutment, 4.8mm, 0° ● Neodent GM Mini Conical Abutment, 4.8mm, max 30° ● Implant Direct GPS® Angled Abutment, 5.0mm, max 30° ● Dentium SuperLine® Abutments, 4.5-5.5mm, max 30° ● Zimmer Angled Tapered Abutments, 4.5mm, max 30° ● Paltop Multi Unit Abutment, 5.0mm, max 17°
Device Material	Titanium alloy Ti-6Al- 4V	Titanium alloy Ti-6Al- 4V
Design/ Technology	CAD/CAM milling from single milling blanks.	CAD/CAM milling from single milling blanks.
Design/ Construction	Patient specific/ machined	Patient specific/ machined
Sterility	Supplied Nonsterile	Supplied Nonsterile
Prescription/ OTC	Prescription only	Prescription only
Recommended Cleaning and Maintenance	Proper oral hygiene	Proper oral hygiene

	Subject Device		Primary Predicate Device	
	Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)		K212676 Osteon Precision Milled Suprastructure Implant Solutions PTY LTD (aka Osteon Medical)	
Design specifications	**Type A**	**Type B**	**Type A**	**Type B**
Total Cylinders	2-10	2-10	2-10	2-10
Suprastructure/Bar Span between Cylinders	1-30 mm	1-30 mm	1-30 mm	1-30 mm
Suprastructure/Bar Height	3-12 mm	3-22 mm	3-12 mm	3-22 mm
Suprastructure/Bar Width	3.4-12 mm	3.4-12 mm	3.4-12 mm	3.4-12 mm
Distal Cantilever Section/ Distal Extension	0-15 mm	0-15 mm	0-15 mm	0-15 mm
Cylinder Height	0-4.6 mm	0-4.6 mm	0-4.6 mm	0-4.6 mm
Cylinder Diameter	4.5-8 mm	4.5-8 mm	4.5-8 mm	4.5-8 mm

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 same methods. The data included in this submission demonstrate substantial equivalence to the predicate and reference devices listed above.