October 26, 2022

Preat Corporation
℅ Chris Brown
Manager
Aclivi, LLC
3250 Brackley Drive
Ann Arbor, Michigan 48105

Re: K220823
Trade/Device Name: Preat Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 21, 2022
Received: September 22, 2022

Dear Chris Brown:

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,

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)*

K220823

Device Name
Preat Abutments

Indications for Use *(Describe)*

Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and the mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Bases or Titanium Blanks are to be sent to a Preat validated milling center for manufacture.

Compatible Implant Systems

Compatible Implant Systems	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
Astra Tech OsseoSpeed™ Plus (OsseoSpeed™ EV)	3.0 (3.0S)	3.0
	3.6 (3.6S)	3.6
	4.2 (4.2C, 4.2S)	4.2
	4.8 (4.8C, 4.8S)	4.8
	5.4 (5.4S)	5.4
Keystone PrimaConnex™	3.5	3.5 (SD)
	4.1	4.1 (RD)
	5.0	5.0 (WD)
Neodent® GM™ Helix	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	3.0
Nobel Biocare™ NobelActive® 3.0	3.0	3.0
Straumann® BLX	3.75, 4.0, 4.5 (RB)	RB
	5.0, 5.5, 6.5 (WB)	WB

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
K220823
Preat Corporation
Preat Abutments
October 26, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Preat Corporation 2625 Skyway Dr, Suite B Santa Maria, CA 93455 Telephone: +1 800 232-7732 Fax: n/a
Official Contact Email:	Chris Bormes, President chris@preat.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Preat Abutments
Common Name:	Abutment, Implant, Dental, Endosseous
Regulation Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3630
Device Class:	Class II
Product Code:	NHA
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The devices within this submission are substantially equivalent in indications, intended use and design principles to the following predicate and reference devices:

510(k)	Predicate Device Name	Company Name
K183518	Preat Abutments	Preat Corporation

510(k)	Reference Device Name	Company Name
K120414	OsseoSpeed™ Plus	Astra Tech AB
K051614	PrimaConnex™ Internal Connection Implant System	Lifecore Biomedical, Inc. (Keystone)
K163194	Neodent Implant System - GM Line	JJGC Industria e Comercio de Materiais Dentarios SA
K180536	Neodent Implant System - GM Line	JJGC Industria e Comercio de Materiais Dentarios SA
K201225	Neodent Implant System - GM Helix Implants 7.0	JJGC Industria e Comercio de Materiais Dentarios SA
K102436	NobelActive® 3.0	Nobel Biocare
K173961	Straumann® BLX Implant System	Institut Straumann AG
K181703	Straumann BLX® Line Extension – Implants, SRAs, and Anatomic Abutments	Institut Straumann AG

INTENDED USE / INDICATIONS FOR USE

Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and the mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Bases or Titanium Blanks are to be sent to a Preat validated milling center for manufacture.

Compatible Implant Systems

Compatible Implant Systems	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
Astra Tech OsseoSpeed™ Plus (OsseoSpeed™ EV)	3.0 (3.0S)	3.0
	3.6 (3.6S)	3.6
	4.2 (4.2C, 4.2S)	4.2
	4.8 (4.8C, 4.8S)	4.8
	5.4 (5.4S)	5.4
Keystone PrimaConnex™	3.5	3.5 (SD)
	4.1	4.1 (RD)
	5.0	5.0 (WD)
Neodent® GM™ Helix	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	3.0
Nobel Biocare™ NobelActive® 3.0	3.0	3.0
Straumann® BLX	3.75, 4.0, 4.5 (RB)	RB
	5.0, 5.5, 6.5 (WB)	WB

DEVICE DESCRIPTION

Preat Abutments were previously cleared under K183518. The purpose of this submission is to obtain marketing clearance for additional compatible implant systems under the Preat Abutments device name. This submission for Preat Abutments is a dental implant abutment system that includes nine (9) abutment designs compatible with five (5) OEM implant systems. The Subject device abutment platform diameters range from 2.9 mm to 5.4 mm, and the corresponding compatible implant body diameters also range from 3.0 mm to 7.0 mm. The Subject device includes the following abutment designs: temporary engaging and non-engaging, multi-unit straight, multi-unit angled 17°, multi-unit angled 30°, engaging and non-engaging titanium base, titanium blank and healing abutments. The system also includes corresponding abutment screws.

The following table shows the Subject device abutments for each of the Compatible implant platforms.

Preat Abutment Platform Diameter/ Compatible Implant System	**Subject Device Abutment Designs**									
	Temp Engaging	**Temp Non-Engaging**	**Multi-Unit Straight**	**Multi-Unit Angled 17°**	**Multi-Unit Angled 30°**	**Titanium Base Engaging**	**Titanium Base Non-Engaging**	**Titanium Blank**	**Healing**	**Titanium Screws**
Astra Tech® OsseoSpeed™ Plus (OsseoSpeed™ EV)										
3.0	X	X	X			X	X	X	X	X
3.6	X	X	X			X	X	X	X	X
4.2	X	X	X			X	X	X	X	X
4.8	X	X	X			X	X	X	X	X
5.4	X	X	X			X	X	X	X	X
Keystone Prima Connex™										
3.5 (SD)	X	X	X	X	X	X	X	X	X	X
4.1 (RD)	X	X	X	X	X	X	X	X	X	X
5.0 (WD)	X	X	X	X	X	X	X	X	X	X
Neodent® GM™ Helix										
3.0	X	X	X	X	X	X	X	X	X	X
Nobel Biocare™ NobelActive®										
3.0	X	X	X	X		X	X	X	X	X
Straumann™ BLX										
RB	X	X	X	X	X	X	X	X	X	X
WB	X	X				X	X	X	X	X

All abutments and screws are manufactured from Ti-6Al-4V ELI alloy conforming to ASTM F136 and are provided non-sterile to the end user. All digitally designed custom abutments for use with Titanium Base (superstructures) or Titanium Blank are to be sent to a Preat validated milling center for manufacture. All superstructures are to be manufactured from zirconia conforming to ISO 13356. Digitally designed CAD/CAM abutments must have a 0.5 mm minimum gingival height dimension.

The Titanium Base abutment is composed of two-piece abutment that is a titanium base at the bottom and a zirconia superstructure (CAD/CAM patient specific superstructure) at the top. The zirconia superstructure is straight only and is not to be designed to provide an angle or divergence correction.

For the Titanium Base abutment, the design parameters for the CAD/CAM zirconia superstructure are:

Minimum wall thickness – 0.5 mm;
Minimum post height for single-unit restorations – 4.0 mm;
Maximum gingival height – 5.0 mm; and

All zirconia superstructures are for straight abutments only.

The design parameters for the CAD/CAM Titanium Blank custom abutment are:

Minimum wall thickness – 0.5 mm to 0.9 mm (varies by implant line);
Minimum post height for single-unit restoration – 4.0 mm;
Maximum Angle – 30°*; and
Minimum gingival height – 0.5 mm;
Maximum gingival height – 2.0 mm to 4.5 mm (varies by implant line).

**Astra Tech® OsseoSpeed™ Plus (OsseoSpeed™ EV) compatible are limited to 0° maximum correction angle.*

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: reverse engineering of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility; static compression and compression fatigue testing according to ISO 14801 and an assessment performed for MR Safety. For each compatible OEM implant line, except Astra Tech OsseoSpeed EV, worst-case constructs were subjected to static compression and compression fatigue testing.

Biocompatibility has been demonstrated through Predicate device testing according to ISO 10993-1, and ISO 10993-5. Sterilization validation was demonstrated through and leveraged from Predicate device testing according to ISO 17665-1 and ISO 14937.

Non-clinical worst-case MRI review was performed to evaluate the Subject device including all compatible implant fixtures, abutments, bars, and fixation screws and their respective material composition in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan, "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795). Rationale addressed parameters per the FDA guidance “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including magnetically induced displacement force and torque.

No clinical or animal data is included in this premarket notification.

EQUIVALENCE TO MARKETED DEVICE

Overall, the Subject device is substantially equivalent in indications and design principles to the Predicate device listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the Subject, Predicate device, and Reference devices.

Subject device abutments are substantially equivalent in intended use to the sponsor's K183518 Predicate device. They are both intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the maxilla and mandible to restore chewing function. Reference devices are also intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the maxilla and mandible to restore chewing function.

The Indications for Use Statement (IFUS) for the Subject device is substantially equivalent to that of the K183518 Predicate device. Differences in the list of compatible implant systems do not affect the intended use of the Subject and Predicate devices to provide support for single or multi-unit prosthetic restorations to restore chewing function.

Similarly, the differences between the Subject device IFUS and that of each Reference device are related to the specific device names and design features. None of these minor differences impact substantial equivalence with the Predicate device because all IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

The following Subject device designs are substantially equivalent to the Predicate device K183518: temporary abutments (engaging and non-engaging); multi-unit straight abutments; multi-unit 17° angulated abutments; titanium base abutments (engaging and non-engaging); and titanium blank abutments.

The Subject and Predicate device abutment designs all have internal implant interface connections and are made of Ti-6Al-4V alloy (abutments and abutment screws). The Subject and Predicate devices each include titanium base abutment designs with a cut out region to allow for angled access to the abutment screw channel. The Predicate device supports abutment designs with angulation of 0° up to 30° by means of titanium blank abutments, validated through performance testing.

The Subject device includes designs for implant restorative platforms ranging from 2.9 mm to 5.4 mm. The Predicate K183518 similarly includes implant restorative platform sizes of 3.0 mm to 6.5 mm.

Reference Device K120414 Astra Tech AB OsseoSpeed™ Plus

The K120414 Reference device is for support of substantial equivalence in terms of the OsseoSpeed™ Plus implant/abutment interface, prosthetic platform diameters and implant diameters. The OsseoSpeed™ Plus was subsequently renamed OsseoSpeed™ EV by the manufacturer, so either name may appear in device labeling or regulatory documentation.

Reference Device K051614 Lifecore Biomedical, Inc. (Keystone) PrimaConnex™ Internal Connection Implant System

The K051614 Reference device is for support of substantial equivalence in terms of the PrimaConnex™ Internal Connection Implant System implant/abutment interface, prosthetic platform diameters and implant diameters. Additionally, K051614 is used to support the addition of Multi-Unit Angled 30° abutments.

Reference Device K163194 JJGC Industria e Comercio de Materiais Dentarios SA Neodent Implant System - GM Line

The K163194 Reference device is for support of substantial equivalence in terms of the Neodent Implant System - GM Line implant/abutment interface, prosthetic platform diameters and implant diameters. Additionally, K163194 is used to support the addition of healing abutments.

Reference Device K102436 Nobel Biocare Nobel Active 3.0
The K102436 Reference device is for support of substantial equivalence in terms of the Nobel Active 3.0 implant/abutment interface, prosthetic platform diameters and implant diameters.

Reference Device K173961 Institut Straumann AG Straumann® BLX Implant System
The K173961 Reference device is for support of substantial equivalence in terms of the Straumann® BLX Implant System implant/abutment interface, prosthetic platform diameters and 4.5 mm, 5.5 mm, and 6.5 mm implant diameters. Furthermore, the K173961 Reference device provides support of substantial equivalence with respect to the use of 30° angulated Multi-Unit and healing abutments.

Reference Device K181703 Institut Straumann AG Straumann® BLX Line Extension – Implants, SRAs and Anatomic Abutments
The K181703 Reference device is for support of substantial equivalence in terms of the Straumann® BLX Implant System implant/abutment interface, prosthetic platform diameters and the 3.75 mm implant diameter.

The Subject device is to be sterilized by the end-user, following the same process as the Predicate device K183518. Validation of the sterilization methods according to ISO 17665-1 and ISO 14937 are leveraged from the K183518 Predicate device.

The Subject device abutment designs are substantially equivalent to those of the K183518 Predicate device. Additional abutment designs, implant/abutment interfaces and dimensions are supported by Reference devices. Minor differences in the abutment designs, dimensions, sizes, or compatible OEM implant lines among the Subject device, the Predicate device, and the Reference devices do not affect substantial equivalence. These minor differences are related to the compatible OEM implant designs and are mitigated by mechanical performance testing.

CONCLUSION
Overall, the Indications for Use statements for the Subject and Predicate devices are substantially equivalent differing only in the list of compatible implant system systems.

Overall, the Technological Characteristics, mode of operation and materials of the Subject device are substantially equivalent to that of the Predicate device with additional compatible implant systems and abutment designs supported by Reference devices.

Overall, the data included in this premarket notification demonstrate substantial equivalence of Preat Abutments to the sponsor's Predicate device.

The basis for the belief that the Subject device is substantially equivalent to the Predicate device and is summarized in the following comparison tables.

Comparison of Indications for Use Statements

<table>
<tr>
<th>Subject Device
Preat Abutments
Preat Corporation</th>
<th>Predicate Device
Preat Abutments
Preat Corporation
K183518</th>
<th>Reference Device
OsseoSpeed™ Plus (OsseoSpeed™ EV)
Astra Tech AB
K120414</th>
<th>Reference Device
PrimaConnex™ Internal Connection Implant System
Lifecore Biomedical, Inc. (Keystone)
K051614</th>
</tr>
<tr>
<td>Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and the mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Bases or Titanium Blanks are to be sent to a Preat validated milling center for manufacture.

Compatible Implant Systems
<table>
<tr><th>Compatible Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr>
<tr><td rowspan="5">Astra Tech OsseoSpeed™ Plus (OsseoSpeed™ EV)</td><td>3.0 (3.0S)</td><td>3.0</td></tr>
<tr><td>3.6 (3.6S)</td><td>3.6</td></tr>
<tr><td>4.2 (4.2C, 4.2S)</td><td>4.2</td></tr>
<tr><td>4.8 (4.8C, 4.8S)</td><td>4.8</td></tr>
<tr><td>5.4 (5.4S)</td><td>5.4</td></tr>
<tr><td rowspan="3">Keystone PrimaConnex</td><td>3.5</td><td>3.5</td></tr>
<tr><td>4.1</td><td>4.1</td></tr>
<tr><td>5.0</td><td>5.0</td></tr>
<tr><td>Neodent GM Helix</td><td>3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0</td><td>3.0</td></tr>
<tr><td>Nobel Biocare™ NobelActive® 3.0</td><td>3.0</td><td>3.0</td></tr>
<tr><td rowspan="2">Straumann™ BLX</td><td>3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB/WB)</td><td>2.9 (RB/WB)</td></tr>
<tr><td>5.0, 5.5, 6.5 (WB)</td><td>2.9 (WB)</td></tr>
</table>
</td>
<td>Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Base or Titanium Blank are to be sent to a Preat validated milling center for manufacture.

Compatible Implant Systems
<table>
<tr><th>Compatible Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr>
<tr><td>3i OSSEOTITE® Certain®</td><td>3.25</td><td>3.4</td></tr>
<tr><td></td><td>4.0</td><td>4.1</td></tr>
<tr><td></td><td>5.0</td><td>5.0</td></tr>
<tr><td></td><td>6.0</td><td>6.0</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>3.0</td><td>3.0</td></tr>
<tr><td></td><td>3.5, 4.0</td><td>3.5, 4.0</td></tr>
<tr><td></td><td>4.5, 5.0</td><td>4.5, 5.0</td></tr>
<tr><td>BioHorizons Tapered Internal</td><td>3.0</td><td>3.0</td></tr>
<tr><td></td><td>3.5</td><td>3.5</td></tr>
<tr><td></td><td>4.0</td><td>4.5</td></tr>
<tr><td>HIOSSEN ET III</td><td>3.5</td><td>Mini</td></tr>
<tr><td></td><td>4.0, 4.5, 5.0, 6.0, 7.0</td><td>Regular</td></tr>
<tr><td>Implant Direct Legacy</td><td>3.2</td><td>3.0</td></tr>
<tr><td></td><td>3.7, 4.2</td><td>3.5</td></tr>
<tr><td></td><td>4.7, 5.2</td><td>4.5</td></tr>
<tr><td></td><td>5.7, 7.0</td><td>5.7</td></tr>
<tr><td>MegaGen AnyRidge</td><td>3.5, 4.0, 4.5, 5.0, 5.5</td><td>3.5</td></tr>
<tr><td>Neoss</td><td>3.5, 4.0, 4.5, 5.0, 5.5</td><td>4.1</td></tr>
<tr><td>NobelActive®</td><td>3.5</td><td>NP</td></tr>
<tr><td></td><td>4.3, 5.0</td><td>RP</td></tr>
<tr><td>Nobel Replace™</td><td>3.5</td><td>NP</td></tr>
<tr><td></td><td>4.0, 4.3, 5.0</td><td>RP</td></tr>
<tr><td></td><td>5.0</td><td>WP</td></tr>
<tr><td></td><td>6.0</td><td>6.0</td></tr>
<tr><td>Straumann® Bone Level</td><td>3.3</td><td>NC</td></tr>
<tr><td></td><td>4.1, 4.8</td><td>RC</td></tr>
<tr><td>Straumann® Tissue Level</td><td>3.3, 4.1, 4.8</td><td>RN</td></tr>
<tr><td></td><td>4.8, 6.5</td><td>WN</td></tr>
<tr><td>Zimmer Screw-Vent®/Tapered Screw-Vent®</td><td>3.3, 3.7, 4.1</td><td>3.5</td></tr>
<tr><td></td><td>4.7</td><td>4.5</td></tr>
<tr><td></td><td>6.0</td><td>5.7</td></tr>
</table>
</td>
<td>Implants:
The Astra Tech Dental Implants are intended for both one- and two-stage surgical procedures in the following situations and with the following clinical protocols:
• replacing single and multiple missing teeth in in the mandible or maxilla,
• immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge,
• especially indicated for use in soft bone applications where implants with other implant surface treatments may be less effective,
• immediate loading for all indications, except in single tooth situations on implants shorter than 8 mm or in soft bone (type IV) where implant stability may be difficult to obtain and immediate loading may not be appropriate.
The intended use for OsseoSpeed™ Plus 3.0S is limited to replacement of maxillary lateral incisors and mandibular incisors.

Abutments:
Astra Tech Implant System Plus abutments are intended to be used in conjunction with Astra Tech Implant System Pus in fully edentulous or partially edentulous maxillary and/or mandibular arches to provide support for crowns, brides or overdentures.

Atlantis Abutments:
The Atlantis™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.

The Atlantis™ Crown Abutment in Zirconia is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in partially or completely edentulous patients. The prosthesis is screw retained. The abutment screw is intended to secure the crown abutment to the endosseous implant.</td>
<td>Lifecore Biomedical Dental Implant System implants are intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.

The PrimaConnex Internal Connection Implant is a threaded internal connection implant. The PrimaConnex Internal Connection Implant is intended for immediate placement, where immediate implant placement is defined by the International Congress of Oral Implantologists (ICOI) as the placement of an implant at the time of tooth extraction, into the extraction socket.

The PrimaConnex Internal Connection Implant is intended for immediate provisionalization, non-occlusal load. Immediate Provisionalization is defined by the International Congress of Oral Implantologists (ICOI) as a clinical protocol for the placement of an interim prosthesis with or without occlusal contact with the opposing dentition, at the same clinical visit of implant placement. The PrimaConnex Internal Connection Implant can be restored with a temporary prosthesis in single tooth and multiple tooth applications with good quality bone.</td>
</tr>
</table>

<table>
<tr>
<th>Subject Device
Preat Abutments
Preat Corporation</th>
<th>Reference Device
Neodent Implant System - GM Line
JJGC Industria e Comercio de Materiais Dentarios SA
K163194</th>
<th>Reference Device
Neodent Implant System - GM Line
JJGC Industria e Comercio de Materiais Dentarios SA
K180536</th>
<th>Reference Device
Neodent Implant System - GM Line
JJGC Industria e Comercio de Materiais Dentarios SA
K201225</th>
</tr>
<tr>
<td>Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and the mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Bases or Titanium Blanks are to be sent to a Preat validated milling center for manufacture.

Compatible Implant Systems
<table>
<tr><th>Compatible Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr>
<tr><td rowspan="5">Astra Tech OsseoSpeed™ Plus (OsseoSpeed™ EV)</td><td>3.0 (3.0S)</td><td>3.0</td></tr>
<tr><td>3.6 (3.6S)</td><td>3.6</td></tr>
<tr><td>4.2 (4.2C, 4.2S)</td><td>4.2</td></tr>
<tr><td>4.8 (4.8C, 4.8S)</td><td>4.8</td></tr>
<tr><td>5.4 (5.4S)</td><td>5.4</td></tr>
<tr><td rowspan="3">Keystone PrimaConnex</td><td>3.5</td><td>3.5</td></tr>
<tr><td>4.1</td><td>4.1</td></tr>
<tr><td>5.0</td><td>5.0</td></tr>
<tr><td>Neodent GM Helix</td><td>3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0</td><td>3.0</td></tr>
<tr><td>Nobel Biocare™ NobelActive® 3.0</td><td>3.0</td><td>3.0</td></tr>
<tr><td rowspan="2">Straumann™ BLX</td><td>3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB/WB)</td><td>2.9 (RB/WB)</td></tr>
<tr><td>5.0, 5.5, 6.5 (WB)</td><td>2.9 (WB)</td></tr>
</table>
</td>
<td>Indications for Use for GM implants and conventional abutments:
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Indications for Use for GM Titanium Base abutments:
Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations.

All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for GM Pro Peek Abutments:
The Pro PEEK Abutments are indicated to be used on Neodent implants to provide temporary support for prosthesis structure for up to 6 months. They can be used in one or two stage procedures and also immediate load when there is good primary stability.</td>
<td>Indications for Use for GM Helix implants and conventional abutments:
The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Indications for Use for GM Exact Titanium Block for Medentika Holder:
GM Exact Titanium Block for Medentika Holder is a titanium abutment to be used in fabricating a full custom abutment and placed onto Neodent dental implants to provide support for customized prosthetic restorations. The GM Exact Titanium Block for Medentika Holder abutments are indicated for screw-retained single restorations or cement-retained single or multi-unit restorations. All digitally designed abutments for use with the GM Exact Titanium Block for Medentika Holder are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for GM Exact Titanium Base abutments:
Titanium Base Abutment is a titanium base placed onto Neodent dental implants to provide support for customized prosthetic restorations. It is used with a coping and crown, or crown alone, and is indicated for cement-retained single or multi-unit restorations, or screw-retained single restorations. All digitally designed copings and/or crowns for use with the Neodent Titanium Base Abutment System are intended to be sent to Straumann for manufacture at a validated milling center.

Indications for Use for Titanium Base C for GM Exact abutments:
The Titanium Base C for GM Exact abutments is a titanium component that is placed over Neodent implants to provide support for custom prosthetic restorations, such as copings or crowns. It is indicated for single-tooth screw-retained restorations. All digitally designed copings and/or crowns for use with the Titanium Base C for GM Exact abutments are to be designed using Sirona inLab software or Sirona CEREC Software and manufactured using a Sirona CEREC or inLab MC X or MC XL milling unit.</td>
<td>The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.</td>
</tr>
</table>

<table>
<tr>
<th>**Subject Device**
Preat Abutments
Preat Corporation</th>
<th>**Reference Device**
NobelActive 3.0
Nobel Biocare
K102436</th>
<th>**Reference Device**
Straumann® BLX Implant System
Institut Straumann AG
K173961</th>
<th>**Reference Device**
Straumann® BLX Line Extension - Implants, SRAs and Anatomic Abutments
Institut Straumann AG
K181703</th>
</tr>
<tr>
<td>Preat Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations. The Titanium Base abutments consists of two major parts. Specifically, the titanium base and the mesostructured components make up a two-piece abutment.

All digitally designed custom abutments, superstructures, and/or hybrid crowns for use with Titanium Bases or Titanium Blanks are to be sent to a Preat validated milling center for manufacture.

Compatible Implant Systems
<table><tr><th>**Compatible Implant Systems**</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr><tr><td rowspan="5">Astra Tech® EV “S” (OsseoSpeed™ Profile EV)</td><td>3.0</td><td>3.0</td></tr><tr><td>3.6</td><td>3.6</td></tr><tr><td>4.2</td><td>4.2</td></tr><tr><td>4.8</td><td>4.8</td></tr><tr><td>5.4</td><td>5.4</td></tr><tr><td rowspan="3">Keystone PrimaConnex™</td><td>3.5</td><td>3.5</td></tr><tr><td>4.1</td><td>4.1</td></tr><tr><td>5.0</td><td>5.0</td></tr><tr><td>Neodent® GM™ Helix</td><td>3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0</td><td>3.0</td></tr><tr><td>Nobel Biocare™ NobelActive® 3.0</td><td>3.0</td><td>3.0</td></tr><tr><td rowspan="2">Straumann™ BLX</td><td>3.75, 4.0, 4.5, 5.0, 5.5, 6.5 (RB/WB)</td><td>2.9 (RB/WB)</td></tr><tr><td>5.0, 5.5, 6.5 (WB)</td><td>2.9 (WB)</td></tr></table></td>
<td>The NobelActive. 3.0mm Implant Is Indicated for use in the treatment of missing maxillary lateral incisors or the mandibular central and lateral incisors to support prosthetic devices, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The NobelActive 3.0 implants may be put into immediate function provided that stability requirements detailed in the manual are satisfied.</td>
<td>Straumann® BLX Implants
Straumann® BLX Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX Implants can be placed with immediate function on single-tooth applications 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.

Straumann® BLX Closure Caps and Healing Abutments Straumann® Closure Caps and Healing Abutments are indicated to be placed in the patient’s mouth at the end of the implant placement to protect the inner configuration of the implant and to shape, maintain and stabilize the soft tissue during the healing process. Closure caps and healing abutments should be used only with suitable implant connections. Straumann Closure Caps and Healing Abutments have a maximum duration of usage of 6 months.

Straumann® BLX Basal Screws and Temporary Abutments
Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they may not be placed into occlusion. Final abutments may be placed into occlusion when the implant is fully osseointegrated. BLX Temporary Abutments have a maximum duration of usage of 180 days.

Straumann® BLX Variobases
Straumann® Variobase® prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. The prosthetic restoration (crowns) can be cemented onto the Straumann® Variobase® prosthetic components. A temporary restoration can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they must be placed out of occlusion. Final abutments and restorations may be placed into occlusion when the implant is fully osseointegrated. All digitally designed copings and/or crowns for use with the Straumann® Variobase® Abutment system are intended to be sent to Straumann for manufacture at a validated milling center.</td>
<td>Straumann® BLX Implants
Straumann® BLX Implants are suitable for endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially edentulous patients. BLX Implants can be placed with immediate function on single-tooth, bar and bridges applications 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.

Straumann® BLX SRAs and Antomic Abutments
Prosthetic components directly or indirectly connected to the endosseous dental implant are intended for use as an aid in prosthetic rehabilitations. Temporary components can be used prior to the insertion of the final components to maintain, stabilize and shape the soft tissue during the healing phase; they may not be placed into occlusion. Final abutments may be placed into occlusion when the implant is fully osseointegrated. BLX Temporary Abutments have a maximum duration of usage of 180 days.</td>
</tr>
</table>

Comparison of Technological Characteristics

Comparison	Subject Device Preat Abutments Preat Corporation	Predicate Device Preat Abutments Preat Corporation K183518	Reference Device OsseoSpeed™ Plus (OsseoSpeed™ EV) Astra Tech AB K120414	Reference Device PrimaConnex™ Internal Connection Implant System Lifecore Biomedical, Inc. (Keystone) K051614	Reference Device Neodent Implant System - GM Line JJGC Industria e Comercio de Materiais Dentarios SA K163194	Reference Device Neodent Implant System - GM Line JJGC Industria e Comercio de Materiais Dentarios SA K180536	Reference Device Neodent Implant System - GM Helix Implants 7.0 JJGC Industria e Comercio de Materiais Dentarios SA K201225
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible	Functional and esthetic rehabilitation of the edentulous maxilla and mandible
Reason for Predicate/Reference	Not Applicable	Abutment configurations listed, 30° post angle correction, sterilization, biocompatibility	Implant/Restorative interface	Implant/Restorative interface, 30 degree Multi-Unit Abutment design.	Helix implant, Implant/Restorative interface, straight screw channel Ti-base configuration, Healing Abutment design	6 mm Helix Implant, Implant/Restorative interface	7 mm Helix Implant, Implant/Restorative interface
Abutment Designs	Temporary Engaging PD = 2.9 - 5.4 mm GH = 1 mm GD = 3.3 - 6.0 mm PH = 10.9 mm (4 mm min)	Temporary Engaging PD = 3.0 – 6.6 mm GH = 1 mm GD = 3.0 – n/d mm PH = 10.9 mm (4 mm min)	Temporary Engaging* PD: 3.0, 3.6, 4.2, 4.8, 5.4 GH: 1 GD: 3.3, 4.0, 4.5, 5.0, 5.5	Temporary Engaging PD: 3.5, 4.1, 5.0 GH: n/d GD: 3.5, 4.1, 5.0	Temporary Engaging PD: 3, 3 GH: 0.8,1.5,2.5,3.5 GD: 3.5, 4.5	n/a	n/a
	Temporary Non-Engaging PD = 2.9 - 5.4 mm GH = 1 mm GD = 3.0 - 6.0 mm PH = 10.9 mm (4 mm min)	Temporary Non-Engaging PD = 3.0 – 6.6 mm GH = 1 mm GD = 3.0 – n/d mm PH = 10 mm (4 mm min)	n/a	Temporary Non-Engaging PD: 3.5, 4.1, 5.0 GH: n/d GD: 3.5, 4.1, 5.0	n/a	n/a	n/a
	Multi-Unit Straight PD = 2.9 - 5.4 mm GH = 1 - 5 mm GD = 4.8 mm PH = 2.2 mm	Multi-Unit Straight PD = 3.0 – 6.6 mm GH = 2 - 5 mm GD = 4.8 mm PH = 2.2 mm	n/a	Multi-Unit Straight PD: 3.5, 4.1, 5.0 GH: 1,2,3 / 1,2,3,4 / 1,2,3,4 GD: 3.5, 4.1, 5.0	Multi-Unit Straight (Mini Conical) PD: 3 GH: 0.8,1.5,2.5,3.5,4.5,5.5 GD: 4.8	n/a	n/a
	Multi-Unit 17° PD = 2.9 - 5.4 mm GH = 2 - 5 mm GD = 4.8 mm PH = 2.2 mm	Multi-Unit 17° PD = 3.0 – 6.6 mm GH = 3.5 – 4.5 mm GD = 4.8 mm PH = 2.2 mm		Multi-Unit 17° PD: 3.5, 4.1, 5.0 GH: 3,4 GD: 3.5, 4.1, 5.0	Multi-Unit 17° (Mini Conical) PD: 3 GH: 3.9,4.9,5.9 GD: 4.8	n/a	n/a
	Multi-Unit 30° PD = 2.9 - 5.4 mm GH = 3 - 4.5 mm GD = 4.8 mm PH = 2.2 mm	n/a	n/a	Multi-Unit 30° PD: 3.5, 4.1, 5.0 GH: 3,4,5 / 3,4,5 / 3,4 GD: 3.5, 4.1, 5.0	Multi-Unit 30° (Mini Conical) PD: 3 GH: 3.9,4.9,5.9 GD: 4.8	n/a	n/a
	Titanium Base Engaging Minimum wall thickness – 0.5 mm; Minimum post height for single-unit restorations – 4.0 mm; Minimum gingival height – 0.5 mm; Maximum gingival height – 5.0 mm; and Straight and Angulated Screw Channel (ASC) variations. All zirconia superstructures are for straight abutments only.	Titanium Base Engaging Minimum wall thickness – 0.5 mm; Minimum post height for single-unit restorations – 4.0 mm; Maximum gingival height – 5.0 mm; and Angulated Screw Channel (ASC) All zirconia superstructures are for straight abutments only.	n/a	n/a	Titanium Base Engaging (GM TiBase) Up to 30° Correction Angle PD: 3, 3, 3 GH: 0.8,1.5,2.5,3.5,4.5 GD: 3.5, 4.5, 5.5 PH = 4, 6 mm Straight screw channel.	Titanium Base Engaging (GM Exact Titanium Base, Titanium Base C) Up to 30° Correction Angle PD: 3, 3 GH: 0.8,1.5,2.5,3.5,4.5,5.5 / 0.8,1.5,2.5,3.5,4.5,5.5 GD: 4.65 (C), 5.5 PH = 4 - 6 mm Straight screw channel	n/a
	Titanium Base Non-Engaging Minimum wall thickness – 0.5 mm; Minimum post height for single-unit restorations – 4.0 mm; Minimum gingival height – 0.5 mm; Maximum gingival height – 5.0 mm; and Straight and Angulated Screw Channel (ASC) variations. All zirconia superstructures are for straight abutments only.	Titanium Base Non-Engaging Minimum wall thickness – 0.5 mm; Minimum post height for single-unit restorations – 4.0 mm; Maximum gingival height – 5.0 mm; and Angulated Screw Channel (ASC)All zirconia superstructures are for straight abutments only.	n/a	n/a	n/a	n/a	n/a

<table>
<tr><td></td><td>Titanium Blank
Minimum wall thickness – 0.5 mm;
Minimum post height for single-unit restoration – 4.0 mm;
Maximum Angle – 30° *;
Minimum gingival height – 0.5 mm; and
Maximum gingival height – 2.0 mm to 4.5 mm (varies by implant line).
*Astra Tech® OsseoSpeed™ Plus (OsseoSpeed™ EV)-compatible 3.0 mm and larger diameter abutments are limited to 0° maximum correction angle.</td><td>Titanium Blank
Minimum wall thickness – 0.5 mm;
Minimum post height for single-unit restoration – 4.0 mm;
Maximum Angle – 30°; and
Maximum gingival height – 1.5 mm to 2.65 mm (varies by implant line).</td><td>n/a</td><td>n/a</td><td>Titanium Blank
Maximum Angle - 30°</td><td>Titanium Blank
Maximum Angle - 30°</td><td>n/a</td></tr>
<tr><td></td><td>Healing
PD = 2.9 - 5.4 mm
GH = 2 - 4 mm
GD = 3.5 - 6.5 mm
PH = 0 mm</td><td>n/a</td><td>Healing
PD = 3.0 – 5.4 mm
GH = n/d
GD = 3.0 – 5.4 mm
PH = n/d</td><td>n/a</td><td>Healing
<table><tr><th>PD</th><th>GH</th><th>GD</th></tr><tr><td>3</td><td>0.8,1.5,2.5,3.5,4.5, 5.5</td><td>4.5</td></tr><tr><td>3</td><td>0.8,1.5,2.5,3.5,4.5, 5.5</td><td>6.0</td></tr></table>PH = n/d</td><td>Healing
<table><tr><th>PD</th><th>GH</th><th>GD</th></tr><tr><td>3</td><td>,1.5,2.5,3.5,4.5,5.5</td><td>5.5</td></tr><tr><td>3</td><td>2.5,3.5,4.5,5.5,6.5</td><td>7.0</td></tr></table>PH = n/d</td><td>n/a</td></tr>
<tr><td>Material (Abutment and Screw)</td><td>Ti-6AL-4V Alloy</td><td>Ti-6AL-4V Alloy</td><td>Titanium Alloy</td><td>Titanium Alloy</td><td>Titanium Alloy</td><td>Titanium Alloy</td><td>Titanium Alloy</td></tr>
<tr><td>Abutment/Implant Interface</td><td>Internal Connection</td><td>Internal Connection</td><td>Internal Connection</td><td>Internal Connection</td><td>Internal Connection</td><td>Internal Connection</td><td>Internal Connection</td></tr>
<tr><td>Prosthesis Attachment</td><td>Cement-retained
Screw-retained</td><td>Cement-retained
Screw-retained</td><td>Cement-retained
Screw-retained</td><td>Cement-retained
Screw-retained</td><td>Cement-retained
Screw-retained</td><td>Cement-retained
Screw-retained</td><td>Cement-retained
Screw-retained</td></tr>
<tr><td>Restoration</td><td>Single-unit
Multi-unit</td><td>Single-unit
Multi-unit</td><td>Single-unit
Multi-unit</td><td>Single-unit
Multi-unit</td><td>Single-unit
Multi-unit</td><td>Single-unit
Multi-unit</td><td>Single-unit</td></tr>
<tr><td>Implant Restorative Platform Diameters (mm)</td><td>2.9-5.4</td><td>3.0-6.6</td><td>3.0, 4.2, 4.8, 5.4</td><td>3.5, 4.1, 5.0</td><td>3.0</td><td>3.0</td><td>3.0</td></tr>
<tr><td>Sterilization Method</td><td>Steam sterilization – End User</td><td>Steam sterilization – End User</td><td>n/d</td><td></td><td>Steam sterilization – End User</td><td>Steam sterilization – End User</td><td>Steam sterilization – End User</td></tr>
</table>

<table>
<tr><th>Comparison</th><th>Subject Device
Preat Abutments
Preat Corporation</th><th>Reference Device
NobelActive 3.0
Nobel Biocare
K102436</th><th>Reference Device
Straumann® BLX Implant System
Institut Straumann AG
K173961</th><th>Reference DeviceStraumann® BLX Line Extension - Implants, SRAs and Anatomic Abutments
Institut Straumann AG
K181703</th></tr>
<tr><td>Intended Use</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td><td>Functional and esthetic rehabilitation of the edentulous maxilla and mandible</td></tr>
<tr><td>Reason for Predicate/Reference</td><td>Not Applicable</td><td>Implant/Restorative interface</td><td>Implant/Restorative interface, 30° Multi-Unit Abutment design, straight screw channel Ti-base configuration, Healing Abutment design</td><td>Implant/Restorative interface, 3.75 mm implant compatibility, and 4.0 mm by being encompassed within 3.75 mm diameter and K173961</td></tr>
<tr><td rowspan="8">Abutment Designs</td><td>Temporary Engaging
PD = 2.9 - 5.4 mm
GH = 1 mm
GD = 3.3 - 6.0 mm
PH = 10.9 mm (4 mm min)</td><td>n/a</td><td>Temporary Engaging<table><tr><th>PD</th><th>GH</th><th>GD</th></tr><tr><td>2.9 (RB/WB)</td><td>1.5,2.5,3.5</td><td>3.8</td></tr><tr><td>2.9 (RB/WB)</td><td>1.5,2.5,3.5</td><td>4.5</td></tr><tr><td>2.9 (RB/WB)</td><td>2.5,3.5</td><td>6.0</td></tr><tr><td>2.9 (WB)</td><td>0.75,1.5</td><td>5.5</td></tr></table></td><td>n/a</td></tr>
<tr><td>Temporary Non-Engaging
PD = 2.9 - 5.4 mm
GH = 1 mm
GD = 3.0 - 6.0 mm
PH = 10.9 mm (4 mm min)</td><td>n/a</td><td>n/a</td><td>n/a</td></tr>
<tr><td>Multi-Unit Straight
PD = 2.9 - 5.4 mm
GH = 1 - 5 mm
GD = 4.8 mm
PH = 2.2 mm</td><td>n/a</td><td>Multi-Unit Straight<table><tr><th>PD</th><th>GH</th><th>GD</th></tr><tr><td>2.9 (RB/WB)</td><td>1.5,2.5,3.5,4.5</td><td>4.6</td></tr></table></td><td>Multi-Unit Straight<table><tr><th>PD</th><th>GH</th><th>GD</th></tr><tr><td>2.9 (RB/WB)</td><td>1.5,2.5,3.5,4.5</td><td>4.6</td></tr></table></td></tr>
<tr><td>Multi-Unit 17°
PD = 2.9 - 5.4 mm
GH = 2 - 5 mm
GD = 4.8 mm
PH = 2.2 mm</td><td>n/a</td><td>Multi-Unit 17°<table><tr><th>PD</th><th>GH</th><th>GD</th></tr><tr><td>2.9 (RB/WB)</td><td>3.5,4.5,5.5</td><td>4.6</td></tr></table></td><td>Multi-Unit 17°<table><tr><th>PD</th><th>GH</th><th>GD</th></tr><tr><td>2.9 (RB/WB)</td><td>2.5,3.5,4.5</td><td>4.6</td></tr></table></td></tr>
<tr><td>Multi-Unit 30°
PD = 2.9 - 5.4 mm
GH = 3 - 4.5 mm
GD = 4.8 mm
PH = 2.2 mm</td><td>n/a</td><td>Multi-Unit 30°<table><tr><th>PD</th><th>GH</th><th>GD</th></tr><tr><td>2.9 (RB/WB)</td><td>3.5,4.5,5.5</td><td>4.6</td></tr></table></td><td>Multi-Unit 30°<table><tr><th>PD</th><th>GH</th><th>GD</th></tr><tr><td>2.9 (RB/WB)</td><td>2.5,3.5,4.5</td><td>4.6</td></tr></table></td></tr>
<tr><td>Titanium Base Engaging
Minimum wall thickness – 0.5 mm;
Minimum post height for single-unit restorations – 4.0 mm;
Minimum gingival height – 0.5 mm;
Maximum gingival height – 5.0 mm; and Straight and Angulated Screw Channel (ASC) variations.
All zirconia superstructures are for straight abutments only.</td><td>n/a</td><td>Titanium Base Engaging (Variobase)
Up to 30° Correction Angle<table><tr><th>PD</th><th>GH</th><th>GD</th></tr><tr><td>2.9 (RB/WB)</td><td>1.5,2.5</td><td>3.8</td></tr><tr><td>2.9 (RB/WB)</td><td>1.5,2.5</td><td>4.5</td></tr><tr><td>2.9 (RB/WB)</td><td>0.75,1.5</td><td>5.5</td></tr><tr><td>2.9 (WB)</td><td>0.75,1.5</td><td>5.5</td></tr></table>Straight screw channel.</td><td>n/a.</td></tr>
<tr><td>Titanium Base Non-Engaging
Minimum wall thickness – 0.5 mm;
Minimum post height for single-unit restorations – 4.0 mm;
Minimum gingival height – 0.5 mm;
Maximum gingival height – 5.0 mm; and Straight and Angulated Screw Channel (ASC) variations.
All zirconia superstructures are for straight abutments only.</td><td>n/a</td><td>n/a</td><td>n/a</td></tr>
</table>

<table>
<tr><td></td><td>Titanium Blank
Minimum wall thickness – 0.5 mm;
Minimum post height for single-unit restoration – 4.0 mm;
Maximum Angle – 30° *;
Minimum gingival height – 0.5 mm; and
Maximum gingival height – 2.0 mm to 4.5 mm (varies by implant line).
*Astra Tech® OsseoSpeed™ Plus (OsseoSpeed™ EV)-compatible 3.0 mm and larger diameter abutments are limited to 0° maximum correction angle.</td><td>n/a</td><td colspan="3">n/a</td><td>n/a</td></tr>
<tr><td></td><td>Healing
PD = 2.9 - 5.4 mm
GH = 2 - 4 mm
GD = 3.5 - 6.5 mm
PH = 0 mm</td><td>n/a</td><td colspan="3">Healing<table><tr><th>PD</th><th>GD</th><th>GH</th><th>AH</th></tr><tr><td rowspan="8">2.9 (RB/WB)</td><td rowspan="2">4.0</td><td>1.5</td><td>2, 4</td></tr><tr><td>2.5</td><td>2, 4</td></tr><tr><td rowspan="2">5.0</td><td>1.5</td><td>2, 4</td></tr><tr><td>2.5</td><td>2, 4</td></tr><tr><td rowspan="3">6.5</td><td>1.5</td><td>2, 4</td></tr><tr><td>2.5</td><td>2, 4</td></tr><tr><td>3.5</td><td>2, 4</td></tr><tr><td rowspan="4">2.9 (WB)</td><td rowspan="2">6.0</td><td>0.75</td><td>2, 4</td></tr><tr><td>1.5</td><td>2, 4</td></tr><tr><td rowspan="2">7.5</td><td>0.75</td><td>2, 4</td></tr><tr><td>1.5</td><td>2, 4</td></tr></table></td><td>n/a</td></tr>
<tr><td>Material (Abutment and Screw)</td><td>Ti-6AL-4V Alloy</td><td>Titanium Alloy</td><td colspan="3">Titanium Alloy</td><td>Titanium Alloy</td></tr>
<tr><td>Abutment/Implant Interface</td><td>Internal Connection</td><td>Internal Connection</td><td colspan="3">Internal Connection</td><td>Internal Connection</td></tr>
<tr><td>Prosthesis Attachment</td><td>Cement-retained
Screw-retained</td><td>Cement-retained
Screw-retained</td><td colspan="3">Cement-retained
Screw-retained</td><td>Cement-retained
Screw-retained</td></tr>
<tr><td>Restoration</td><td>Single-unit
Multi-unit</td><td>Single-unit</td><td colspan="3">Single-unit
Multi-unit</td><td>Single-unit
Multi-unit</td></tr>
<tr><td>Implant Restorative Platform Diameters (mm)</td><td>2.9-5.4</td><td>3.0</td><td colspan="3">2.9 (RB/WB)
2.9 (WB)</td><td>2.9 (RB/WB)</td></tr>
<tr><td>Sterilization Method</td><td>Steam sterilization – End User</td><td></td><td colspan="3">Steam sterilization – End User</td><td>Steam sterilization – End User</td></tr>
</table>

PD = Abutment/Implant Platform diameter
GH = Gingival Height
GD = Gingival Diameter (Prosthetic Diameter)
n/d = not defined in literature or 510(k) summary
*According to device labeling