Preat Corporation
% Kevin Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

March 18, 2019

Re: K183518
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: December 17, 2018
Received: December 18, 2018

Dear Kevin Thomas:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.03.18 16:42:18 -04'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K183518

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 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

Compatible Implant System	**Implant Body Diameter (mm)**	**Implant Platform Diameter (mm)**
3i OSSEOTITE® Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
	6.0	6.0
Astra Tech OsseoSpeed™	3.0	3.0
	3.5, 4.0	3.5/4.0
	4.5, 5.0	4.5/5.0
BioHorizons Tapered Internal	3.0	3.0
	3.5	3.5
	4.0	4.5
HIOSSEN ET III	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Implant Direct Legacy	3.2	3.0
	3.7, 4.2	3.5
	4.7, 5.2	4.5
	5.7, 7.0	5.7
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neoss	3.5, 4.0, 4.5, 5.0, 5.5	4.1
NobelActive®	3.5	NP
	4.3, 5.0	RP
Nobel Replace™	3.5	NP
	4.0, 4.3, 5.0	RP
	5.0	WP
	6.0	6.0
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Straumann® Tissue Level	3.3, 4.1, 4.8	RN
	4.8, 6.5	WN
Zimmer Screw-Vent®/Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

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

K183518 – Preat Abutments

Preat Corporation

March 18, 2019

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Preat Abutments
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 Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary Predicate
K170588, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K120414, OsseoSpeed™ Plus, Astra Tech AB
K161416, Multi-unit Abutment Plus, Nobel Biocare AB
K151621, BioHorizons CAD/CAM Abutments, BioHorizons Implant Systems, Inc.
K100993, Inclusive® Titanium Abutments for Astra OsseoSpeed™, Prismatik Dentalcraft, Inc.

INDICATIONS FOR USE STATEMENT

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

Compatible Implant System	**Implant Body Diameter (mm)**	**Implant Platform Diameter (mm)**
3i OSSEOTITE® Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
	6.0	6.0
Astra Tech OsseoSpeed™	3.0	3.0
	3.5, 4.0	3.5/4.0
	4.5, 5.0	4.5/5.0
BioHorizons Tapered Internal	3.0	3.0
	3.5	3.5
	4.0	4.5
HIOSSEN ET III	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Implant Direct Legacy	3.2	3.0
	3.7, 4.2	3.5
	4.7, 5.2	4.5
	5.7, 7.0	5.7
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neoss	3.5, 4.0, 4.5, 5.0, 5.5	4.1
NobelActive®	3.5	NP
	4.3, 5.0	RP
Nobel Replace™	3.5	NP
	4.0, 4.3, 5.0	RP
	5.0	WP
	6.0	6.0
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Straumann® Tissue Level	3.3, 4.1, 4.8	RN
	4.8, 6.5	WN
Zimmer Screw-Vent®/Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

SUBJECT DEVICE DESCRIPTION

Preat Abutments is a dental implant abutment system that includes ten (10) abutment designs compatible with twelve (12) OEM implant systems. The subject device abutment platform diameters range from 3.0 mm to 6.5 mm, and the corresponding compatible implant body diameters also range from 3.0 mm to 6.5 mm. The subject device includes the following abutment designs: temporary, esthetic angled 15°, multi-

unit straight, multi-unit angled 17°, ball (Clix Ball and O-Ring), titanium base, and titanium blank. The system also includes corresponding abutment screws.

The following table shows the subject device abutments platform sizes for each of the OEM implant lines and sizes.

Preat Abutment Platform Diameter / Compatible Implant System	Subject Device Abutment Designs										
	Temporary Engaging	Temporary Non-Engaging	Esthetic Angled 15°	Multi- Unit Straight	Multi-Unit Angled 17°	Clix Ball	O-Ring	Titanium Base Engaging	Titanium Base Non-Engaging	Titanium Blank	Titanium Screws
3i OSSEOTITE® Certain®											
3.4	X	X		X	X	X	X	X	X	X	X
4.1	X	X		X	X	X	X	X	X	X	X
5.0	X	X		X	X			X	X	X	X
6.0	X	X						X	X	X	X
Astra Tech OsseoSpeed™											
3.0	X	X						X	X	X	X
3.5/4.0	X	X	X	X	X	X	X	X	X	X	X
4.5/5.0	X	X	X	X	X	X	X	X	X	X	X
BioHorizons Tapered Internal											
3.0	X	X		X	X			X	X	X	X
3.5	X	X			X	X	X	X	X	X	X
4.5	X	X			X	X	X	X	X	X	X
HIOSSEN ET III											
Mini	X	X		X	X			X	X	X	X
Regular	X	X		X	X			X	X	X	X
Implant Direct Legacy											
3.0				X	X			X	X	X	X
3.5	X	X			X	X	X	X	X	X	X
4.5	X	X			X	X	X	X	X	X	X
5.7	X	X						X	X	X	X
MegaGen AnyRidge											
3.5	X	X		X	X			X	X	X	X
Neoss											
4.1	X	X		X	X	X	X	X	X	X	X
NobelActive®											
NP	X	X		X	X	X	X	X	X	X	X
RP	X	X		X	X	X	X	X	X	X	X
Nobel Replace™											
NP	X	X		X	X	X	X	X	X	X	X
RP	X	X		X	X	X	X	X	X	X	X
WP	X	X		X		X	X	X	X	X	X
6.0										X	X
Straumann® Bone Level											
NC	X	X		X	X	X	X	X	X	X	X
RC	X	X		X	X	X	X	X	X	X	X
Straumann® Tissue Level											
RN	X	X				X	X	X	X	X	X
WN										X	X
Zimmer Screw-Vent®/ Tapered Screw-Vent®											
3.5	X	X		X	X	X	X	X	X	X	X
4.5	X	X		X	X	X	X	X	X	X	X
5.7	X	X						X	X	X	X

All abutments and screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 and are provided non-sterile to the end user. 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. All superstructures are to be manufactured from zirconia conforming to ISO 13356.

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;
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).

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1 and ISO 14937; biocompatibility according to ISO 10993-5 and ISO 10993-12; reverse engineering of OEM implant bodies, abutment, and abutment screws to confirm compatibility; and static compression and compression fatigue testing according to ISO 14801. 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 and the reference devices listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

Subject device abutments are substantially equivalent in intended use to the primary predicate K170588, and the reference devices K120414, K161416, K151621, and K100993. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible.

The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of the primary predicate K170588. Slight differences in language of the subject device and primary predicate device Indications for Use statements do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function. The minor differences between the IFUS for the subject device and the primary predicate include: the subject device IFUS includes the term “single-unit or multi-unit” and the primary predicate IFUS does not. The other minor differences are

related to the specific device names, validated milling centers, and the compatible OEM implant lines. None of these minor differences impact substantial equivalence because both IFUS express equivalent intended use to facilitate dental prosthetic restorations, and the indications are expressed equivalently using different specific wording.

Similarly, the differences between the subject device IFUS and that of each of the reference devices are related to the specific device names and design features, validated milling centers, and the compatible implant lines. None of these minor differences impact substantial equivalence 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 primary predicate device K170588: temporary abutments; multi-unit straight abutments; titanium base abutments; and titanium blank abutments. The subject device and the primary predicate device K170588 are for single-unit or multi-unit restorations, have internal implant interface connections, and are made of Ti-6Al-4V alloy (abutments and abutment screws). The primary predicate includes straight abutments only. The subject device includes angled abutments up to 30° and the substantial equivalence of this angulation is supported by each of the reference devices.

The subject device includes designs for implant platforms ranging from 3.0 mm to 6.5 mm. The primary predicate K170588 includes implant platform sizes of 3.4 mm to 6.5 mm. Substantial equivalence of the smaller implant platform sizes of the subject device are supported by the reference devices K120414, K151621, and K100993.
The following subject device designs are substantially equivalent to those of the reference device K120414: temporary abutments; esthetic abutments (angled 15°); multi-unit straight abutments; and ball abutments. The subject device and the reference device K120414 abutments are for single-unit or multi-unit restorations, include angulations up to 30°, have internal implant interface connections, and are made of Ti-6Al-4V alloy (abutments and abutment screws).

The subject device multi-unit angled abutments are substantially equivalent to those of the reference device K161416. The subject device and the reference device K161416 each include multi-unit abutments angled 17°, have internal implant interface connections, and are made of Ti-6Al-4V alloy (abutments and abutment screws).

The subject device titanium base abutments are substantially equivalent to those of the reference device K151621. The subject device and the reference device K151621 each include titanium base abutment designs with a cut out region to allow for angled access to the screw channel for multi-unit restorations. The subject device and the reference device K151621 titanium base designs have internal implant interface connections, and are made of Ti-6Al-4V alloy (abutments and abutment screws).
The reference device K100993 is for support of substantial equivalence in terms of mechanical performance as discussed below. The subject device and the reference device K100993 titanium blank abutment designs with angulation of up to 30°, are for internal implant interface connections, and are made of Ti-6Al-4V alloy (abutments and abutment screws).

The subject device is to be sterilized by the end-user, the same as the primary predicate device K170588. Sterilization validation for the subject device was performed according to ISO 17665-1 and ISO TR 17665-2. This sterilization validation method is the same as the primary predicate device K170588.

Confirmatory biocompatibility testing of the subject device was performed according to ANSI / AAMI / ISO 10993-5 and 10993-12.

Mechanical performance testing was performed according to ISO 14801. For each compatible OEM implant line, worst-case constructs were subjected to static compression and compression fatigue testing. The reference device K100993 is to support substantial equivalence of the fatigue limit of 133 N for the Astra Tech OsseoSpeed™ and BioHorizons Tapered Internal implant lines (each with 3.0 mm implant body and platform diameters). The fatigue limit data for all other implant lines demonstrated the construct strengths to be sufficient for their intended use.

Minor differences in the designs, dimensions, sizes, or compatible OEM implant lines among the subject device, the primary predicate device, and the reference devices do not affect substantial equivalence. These minor differences do not impact substantial equivalence because these differences are related to the compatible OEM implant designs, or are mitigated by the mechanical performance testing.

CONCLUSION

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

Comparison of Indications for Use Statements

Subject Device

Preat Abutments

Preat Corporation

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.
All digitally designed custom abutments for use with Titanium Base or Titanium Blank are to be sent to a Preat validated milling center for manufacture.

Compatible Implant Systems

Compatible Implant System	Implant Body Diameter (mm)	Implant Platform Diameter (mm)
3i OSSEOTITE® Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
	6.0	6.0
Astra Tech OsseoSpeed™	3.0	3.0
	3.5, 4.0	3.5/4.0
	4.5, 5.0	4.5/5.0
BioHorizons Tapered Internal	3.0	3.0
	3.5	3.5
	4.0	4.5
HIOSSEN ET III	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Implant Direct Legacy	3.2	3.0
	3.7, 4.2	3.5
	4.7, 5.2	4.5
	5.7, 7.0	5.7
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neoss	3.5, 4.0, 4.5, 5.0, 5.5	4.1
NobelActive®	3.5	NP
	4.3, 5.0	RP
Nobel Replace™	3.5	NP
	4.0, 4.3, 5.0	RP
	5.0	WP
	6.0	6.0
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Straumann® Tissue Level	3.3, 4.1, 4.8	RN
	4.8, 6.5	WN
Zimmer Screw-Vent®/Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

Primary Predicate

K170588
DESS Dental Smart Solutions

Terrats Medical SL

DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.
All digitally designed custom abutments for use with TiBase or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Platform Diameter (mm)
3i Certain®	3.25, 4.0, 5.0	3.4, 4.1, 5.0
3i OSSEOTITE®	3.25, 3.75, 4.0, 5.0	3.4, 4.1, 5.0
OsseoSpeed™	3.5, 4.0, 5.0	3.5/4.0, 4.5/5.0
FRIADENT XiVE	3.4, 3.8, 4.5	3.4, 3.8, 4.5
NobelActive®	3.5, 4.3, 5.0	NP, RP
NobelReplace Conical	3.5, 4.3, 5.0	NP, RP
Nobel Replace Trilobe	3.5, 4.3, 5.0	NP, RP, WP
Brånemark	3.5, 3.75/4.0, 5.0	NP, RP, WP
Straumann® Bone Level	3.3, 4.1, 4.8	NC, RC
Straumann® Tissue Level	3.3, 4.1, 4.8	RN, WN
Tapered Screw-Vent®	3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7

Reference Device

K120414
OsseoSpeed™ Plus

Astra Tech AB

(Implant section of IFUS not applicable to this submission)

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

Reference Device

K161416
Multi-unit Abutment Plus

Nobel Biocare

The Multi-unit Abutment Plus is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Reference Device

K151621
BioHorizons CAD/CAM Abutments

BioHorizons Implant Systems, Inc.

BioHorizons CAD/CAM Abutments are dental abutments placed onto a dental implant to provide support for dental prosthetic restorations. The abutments include: 1) Titanium abutment blanks with a pre-machined implant connection where the upper portion may be custom-milled in accordance with a patient-specific design using CAD/CAM techniques; and 2) Titanium bases with a pre-machined implant connection upon which a CAD/CAM designed superstructure may be fitted to complete a two-piece dental abutment. The abutments include an abutment screw for fixation to the underlying implant. The abutments may be used for single-unit (single-tooth) or multiple-unit (bridges and bars) restorations and are compatible for use with BioHorizons Internal and Tapered Internal implant systems and Zimmer® Dental Screw-Vent® and Tapered Screw-Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex-connection mating platform diameters.

All digitally designed abutments and/or copings for use with BioHorizons CAD/CAM Abutments are intended to be sent to a BioHorizons-validated milling center for manufacture. BioHorizons abutments designed using CAD/CAM techniques must fulfill the BioHorizons allowable range of design parameters.

Reference Device

K100993
Inclusive® Titanium Abutments for Astra OsseoSpeed™
Prismatik Dentalcraft, Inc.

The Inclusive® Titanium Abutments for Astra OsseoSpeed™ Implants are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for use as an aid in prosthetic rehabilitation. They are compatible with the Astra Tech OsseoSpeed™ 3.0, 3.5, 4.0, 4.5, 5.0 implants.

Comparison of Technological Characteristics

Comparison	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device	Reference Device
	Preat Abutments Preat Corporation	K170588 DESS Dental Smart Solutions Terrats Medical SL	K120414 OsseoSpeed™ Plus Astra Tech AB	K161416 Multi-unit Abutment Plus Nobel Biocare	K151621 BioHorizons CAD/CAM Abutments BioHorizons Implant Systems, Inc.	K100993 Inclusive® Titanium Abutments for Astra OsseoSpeed™ Prismatik Dentalcraft, Inc.
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
Reason for Predicate/Reference	Not applicable	Abutment designs listed	Abutment designs listed	Abutment design listed	Abutment design listed	Abutment design listed Performance testing data
Abutment Designs	Temporary Engaging	Temporary Engaging	Temporary			
	Temporary Non-Engaging	Temporary Non-Engaging				
	Esthetic Angled 15°		Esthetic 15°			
	Multi-Unit Straight	Multi-unit Straight	Multi-unit Straight			
	Multi-Unit Angled 17°			Multi-unit 17°		
	Ball (Clix, O-Ring)		Ball			
	Titanium Base Engaging	Titanium Base Engaging			Titanium Base	
	Titanium Base Non-Engaging	Titanium Base Non-Engaging				
	Titanium Blank (Engaging)	Titanium Blank (Engaging)				Titanium Blank (Engaging)
Prosthesis Attachment	Cement-retained Screw-retained	Not stated in 510(k) Summary	Not stated in 510(k) Summary	Screw-retained	Cement-retained	Cement-retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Multi-unit	Single-unit Multi-unit	Not stated in 510(k) Summary
Abutment/Implant Platform Diameter (mm)	3.0 – 6.5	3.4 – 6.5	3.0 – 5.4	NP, RP, WP (3.5 – 5.0)	3.0 – 5.7	3.0 – 5.0
Abutment Angle	Straight (0°), 15°, 17°, and 30° maximum (Titanium Blank)	Straight (0°)	Straight (0°), angled to 30°	Straight (0°), 17°, 30°	Straight (0°), angled to 30°	Straight (0°), angled to 30°
Abutment/ Implant Interface	Internal connection	Internal connection; External connection	Internal connection	Internal connection	Internal connection	Internal connection
Materials						
Abutment	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy, Zirconia, Gold, PEEK	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy
Screw	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy