



May 8, 2025

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

Re: K243824

Trade/Device Name: Preat Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: December 12, 2024
Received: April 8, 2025

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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

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.

All digitally designed CAD/CAM customizations for Preat Abutments are intended to be sent to a Preat validated Milling Center for manufacture or to be designed and manufactured according to a validated digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

Preat Abutments are compatible with the following third-party implant restorative platforms:

Compatible Third-Party Implant Systems	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
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
BioHorizons® Tapered Internal	3.0	3.0
	3.5	3.5
	4.0	4.5
HIOSEN 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
Keystone PrimaConnex™	3.5	3.5 (SD)
	4.1	4.1 (RD)
	5.0	5.0 (WD)
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neodent® GM™ Helix	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	3.0
Neoss	3.5, 4.0, 4.5, 5.0, 5.5	4.1
Nobel Biocare™ NobelActive®	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
Nobel Biocare™ NobelReplace®	3.5	NP
	4.0, 4.3, 5.0	RP
	5.0	WP
	6.0	6.0
Straumann™ BLX	3.75, 4.0, 4.5 (RB)	RB
	5.0, 5.5, 6.5 (WB)	WB
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
	3.3, 3.7, 4.1	3.5
Zimmer Screw-Vent®/ Tapered Screw-Vent®	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 – K243824
Preat Corporation
Preat Abutments
May 7, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name Preat Corporation
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Fax: n/a

Official Contact Nicholas Grassel, Manager-Product Development
Email: ngrassel@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, PNP

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 Primary Predicate and Reference devices:

510(k)	Primary Predicate Device Name	Company Name
K220823	Preat Abutments	Preat Corporation
510(k)	Reference Device Name	Company Name
K183518	Preat Abutments	Preat Corporation
K222044	Elos Accurate® Customized Abutment	Elos Medtech Pinol A/S
K200100	Abutment Design	3Shape A/S
K193352	Abutmentcad	Exocad GmbH

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.

All digitally designed CAD/CAM customizations for Preat Abutments are intended to be sent to a Preat validated Milling Center for manufacture or to be designed and manufactured according to a validated digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, milling machine and associated tooling and accessories.

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	6.0	6.0
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	3.5, 4.0	3.5/4.0
	4.5, 5.0	4.5/5.0
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
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Neoss	3.5, 4.0, 4.5, 5.0, 5.5	4.1
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Zimmer Screw-Vent®/ Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

DEVICE DESCRIPTION

The purpose of this submission is to expand the use of Preat Abutments, specifically the titanium blank abutment design, to be used in a validated equipment CAD/CAM workflow where specific abutment design software, milling machines and tooling have been validated to work with the previously cleared components in K220823 and K183518.

This submission includes a titanium blank design which is compatible with sixteen (16) implant system, with a distinct connection platform, as well as varying implant diameters and implant platform diameters, for each system.

The Subject device abutments may be placed in implants located in the mandibular or maxillary arches. The Subject device abutments are compatible with implant body diameters that range from 3.0 mm to 7.0 mm and implant platform diameters which range from 2.9 to 6.0 mm.

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.

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 restorations (length above the abutment collar / gingival height)– 4.0 mm;
- Maximum Angle – 30°*; and
- Minimum gingival height – 0.5 mm;
- Maximum gingival height – 1.5 mm to 4.5 mm (varies by implant line).

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

The minimum and maximum abutment design parameters listed above correspond to the abutment designs used in the mechanical testing data provided in the sponsor's K220823 and K183518 device submissions.

All digitally designed CAD/CAM customizations for Preat Abutments are intended to be sent to a Preat validated Milling Center for manufacture or to be designed and manufactured according to a validated digital dentistry workflow which includes: Scan files from Intra-Oral and Desktop Scanners, CAD software, CAM software, a Milling machine and associated tooling and accessories.

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.

Software verification included testing of restrictions that prevent design of components outside of the stated design parameters. In addition, the abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified by the user. To address the potential risk of damage to the implant-abutment connection geometry during the milling of the patient-matched portions of the abutment blanks, validation testing of the CAM restriction zones was conducted, including verification to show avoidance of damage or modifications of the connection geometry, and locking of restriction zones from user editing in the CAM software.

Biocompatibility has been demonstrated through the sponsor's K220823 device testing according to ISO 10993-1, and ISO 10993-5. Sterilization validation was demonstrated through and leveraged from the sponsor's K220823 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

The Subject device is substantially equivalent in Indications for Use, Technological Characteristics and design principles to Primary Predicate and Reference devices listed above. The Summary tables at the end of this section compare the Subject device and Primary Predicate/Reference devices.

Indications for Use

The Indications for Use Statement (IFUS) of the Subject device combines the compatible implant systems of the sponsor's K220823 and K183518 Indications for Use Statements. The intended use with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations is the same for the Subject device and the sponsor's K220823 and K183518 devices. The Subject device does not include titanium base abutments which are included in the K220823 and K183518 submissions, so it does not reference this abutment design in the IFUS. The Subject device and the sponsor's K220823 and K183518 devices share the same intention to be sent to a Preat validated milling center for final manufacturing.

The IFUS of the Subject device and the K222044 Reference device are highly similar. They both share the same intended use in conjunction with dental implants to provide support for single-unit or multi-unit prosthetic restorations. They both share a common intention of the design and manufacturing of the final abutment by means of a defined, digital dentistry validated workflow. The Subject device and K222044 Reference device share similar compatible implant systems. Additionally, the Subject device lists both intra-oral and laboratory scanners as opposed to only intra-oral. Differences in compatible implant systems, and types of scanners identified in the workflow, do not change the intended use of the Subject and Reference device to provide support for single or multi-unit prosthetic restorations to restore chewing function.

None of the minor differences in Indications for Use Statements 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.

Technological Characteristics

Overall, the Subject device is highly similar to the Primary Predicate and Reference devices. The FDA product code, device regulation and intended use of the Subject, Primary Predicate and Reference devices to provide functional and esthetic rehabilitation of the maxilla and mandible to restore chewing function are the same for the Primary Predicate and Reference devices.

Primary Predicate Device K220823 Preat Corporation Preat Abutments

The Subject and K220823 Primary Predicate device titanium abutment design is the same. The list of K220823 compatible implants and platform diameters are included in the Subject device. Subject device abutment design parameters for the common compatible implant systems are the same as the K220823 device. The Subject device materials, connection type, prosthesis attachment, supported restoration type, biocompatibility and sterilization method are the same as the K220832 device. The minimum Subject device compatible implant platform diameter is supported by the K220832 device. The Subject and K220832 device are intended to be manufactured by means of a validated milling center workflow. The Subject device differs in that it may also be manufactured by means of a validated digital dentistry workflow. This minor difference in manufacturing process does not impact the substantial equivalence of the intended use of the device and is supported by non-clinical bench testing and workflow software/equipment validation.

Reference Device K183518 Preat Corporation Preat Abutments

The Subject and K183518 Reference device titanium abutment design is the same. The list of K183518 compatible implants and platform diameters are included in the Subject device. Subject device abutment design parameters for the common compatible implant systems are the same as the K183518 Reference device. The Subject device materials, connection type, prosthesis attachment, supported restoration type, biocompatibility and sterilization method are the same as the K183518 Reference device. The maximum Subject device compatible implant platform diameter is supported by the K183518 Reference device. The Subject and K183518 Reference device are intended to be manufactured by means of a validated milling center workflow. The Subject device differs in that it may also be manufactured by means of a validated digital dentistry workflow. This minor difference in manufacturing process does not impact the substantial equivalence of the intended use of the device and is supported by non-clinical bench testing and workflow software/equipment validation.

Reference Device K222044 Elos Medtech Pinol A/S Elos Accurate® Customized Abutment

The Subject and K222044 Reference device titanium abutment design are highly similar. The list of K222044 compatible implants and platform diameters are similar to the Subject device. Subject device abutment design parameters are similar to the K222044 Reference device. The Subject device materials, connection type, prosthesis attachment, and supported restoration types are the same as the K222044 Reference device. The Subject and K222044 Reference device are intended to be manufactured by means of a validated digital dentistry workflow which adds the secondary PNP product code. The validated digital dentistry workflow of the Subject device is supported by the K222044 Reference device and is also supported by non-clinical bench testing and workflow software/equipment validation.

Ultimately there are no changes to the technology, mode of action, intended use or design parameters of the Subject device relative to sponsor's Primary Predicate and Reference devices. The only difference between the Primary Predicate and Reference devices and the Subject device is the additional option of being manufactured by means of a validated digital dentistry workflow. The digital dentistry workflow path is supported by the K222044 Reference device and validated through non-clinical bench testing and workflow software/equipment validation.

CONCLUSION

Overall, the Indications for Use statements for the Subject, Primary Predicate and Reference devices are highly similar.

Overall, the Technological Characteristics, mode of operation and materials of the Subject device are substantially equivalent to that of the sponsor's Primary Predicate device with the additional compatible implant systems supported by sponsor's Reference device. The design and manufacturing workflows of the Subject and K222044 Reference device are highly similar.

Overall, the data included in this premarket notification demonstrates substantial equivalence of the Subject device to the sponsor's Primary Predicate device with digital dentistry workflow technology supported by the K222044 Reference device. Any differences between the Primary Predicate and Reference device digital dentistry workflows are supported by non-clinical bench testing. The basis for the belief that the Subject device is substantially equivalent to the Primary Predicate device and is summarized in the following comparison tables.

Comparison of Indications for Use Statements

Subject Device Preat Abutments Preat Corporation	Primary Predicate Device Preat Abutments Preat Corporation K220823	Reference Device Preat Abutments Preat Corporation K183518																																																																																																																																																																																																																																															
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Internal	3.0	3.0	3.5	3.5	4.0	4.5	HIOSEN 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	Keystone PrimaConnex™	3.5	3.5 (SD)	4.1	4.1 (RD)	5.0	5.0 (WD)	MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5	Neodent® GM™ Helix	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	3.0	Neoss	3.5, 4.0, 4.5, 5.0, 5.5	4.1	Nobel Biocare™ NobelActive®	3.0	3.0	3.5	NP	4.3, 5.0	RP	Nobel Biocare™ NobelReplace®	3.5	NP	4.0, 4.3, 5.0	RP	5.0	WP	6.0	6.0	Straumann™ BLX	3.75, 4.0, 4.5 (RB)	RB	5.0, 5.5, 6.5 (WB)	WB	Straumann® Bone Level	3.3	NC	4.1, 4.8	RC	3.3, 4.1, 4.8	RN	Straumann® Tissue Level	4.8, 6.5	WN	3.3, 3.7, 4.1	3.5	Zimmer Screw-Vent®/ Tapered Screw-Vent®	4.7	4.5	6.0	5.7	<table border="1"> <thead> <tr> <th colspan="3">Compatible Implant Systems</th></tr> <tr> <th>Compatible Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr> </thead> <tbody> <tr><td rowspan="5">Astra Tech OsseoSpeed™ Plus (OsseoSpeed™ 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PrimaConnex	3.5	3.5	4.1	4.1	5.0	5.0	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, 5.0, 5.5, 6.5 (RB/WB)	2.9 (RB/WB)	5.0, 5.5, 6.5 (WB)	2.9 (WB)	<table border="1"> <thead> <tr> <th colspan="3">Compatible Implant Systems</th></tr> <tr> <th>Compatible Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr> </thead> <tbody> <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>HIOSEN ET 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Neoss	3.5, 4.0, 4.5, 5.0, 5.5	4.1																																																																																																																																																																																																																																															
NobelActive®	3.5	NP																																																																																																																																																																																																																																															
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Nobel Replace™	3.5	NP																																																																																																																																																																																																																																															
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Straumann® Bone Level	3.3	NC																																																																																																																																																																																																																																															
	4.1, 4.8	RC																																																																																																																																																																																																																																															
Straumann® Tissue Level	3.3, 4.1, 4.8	RN																																																																																																																																																																																																																																															
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Zimmer Screw-Vent®/Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5																																																																																																																																																																																																																																															
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Subject Device	Reference Device																																																																																																																																																																					
Preat Abutments Preat Corporation	Elos Accurate® Customized Abutment Elos Medtech Pinol A/S K222044																																																																																																																																																																					
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 Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw.																																																																																																																																																																					
All digitally designed CAD/CAM customizations for Preat Abutments are intended to be sent to a Preat validated Milling Center for manufacture or to be designed and manufactured according to a validated digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, milling machine and associated tooling and accessories.	The Elos Accurate® Customized Abutments are compatible with the implant systems listed in Table 1:																																																																																																																																																																					
Preat Abutments are compatible with the following third-party implant restorative platforms:	Table 1.																																																																																																																																																																					
<table><tr><th>Compatible Third-Party Implant Systems</th><th>Implant Body Diameter (mm)</th><th>Implant Platform Diameter (mm)</th></tr><tr><td rowspan="4">3i OSSEOTITE® Certain®</td><td>3.25</td><td>3.4</td></tr><tr><td>4.0</td><td>4.1</td></tr><tr><td>5.0</td><td>5.0</td></tr><tr><td>6.0</td><td>6.0</td></tr><tr><td rowspan="3">Astra Tech OsseoSpeed™</td><td>3.0</td><td>3.0</td></tr><tr><td>3.5, 4.0</td><td>3.5/4.0</td></tr><tr><td>4.5, 5.0</td><td>4.5/5.0</td></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">BioHorizons® Tapered Internal</td><td>3.0</td><td>3.0</td></tr><tr><td>3.5</td><td>3.5</td></tr><tr><td>4.0</td><td>4.5</td></tr><tr><td rowspan="2">HIOSSEN ET III</td><td>3.5</td><td>Mini</td></tr><tr><td>4.0, 4.5, 5.0, 6.0, 7.0</td><td>Regular</td></tr><tr><td rowspan="4">Implant Direct Legacy</td><td>3.2</td><td>3.0</td></tr><tr><td>3.7, 4.2</td><td>3.5</td></tr><tr><td>4.7, 5.2</td><td>4.5</td></tr><tr><td>5.7, 7.0</td><td>5.7</td></tr><tr><td rowspan="3">Keystone PrimaConnex™</td><td>3.5</td><td>3.5 (SD)</td></tr><tr><td>4.1</td><td>4.1 (RD)</td></tr><tr><td>5.0</td><td>5.0 (WD)</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>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>Neoss</td><td>3.5, 4.0, 4.5, 5.0, 5.5</td><td>4.1</td></tr><tr><td rowspan="3">Nobel Biocare™ NobelActive®</td><td>3.0</td><td>3.0</td></tr><tr><td>3.5</td><td>NP</td></tr><tr><td>4.3, 5.0</td><td>RP</td></tr><tr><td rowspan="4">Nobel Biocare™ NobelReplace®</td><td>3.5</td><td>NP</td></tr><tr><td>4.0, 4.3, 5.0</td><td>RP</td></tr><tr><td>5.0</td><td>WP</td></tr><tr><td>6.0</td><td>6.0</td></tr><tr><td rowspan="2">Straumann™ BLX</td><td>3.75, 4.0, 4.5 (RB)</td><td>RB</td></tr><tr><td>5.0, 5.5, 6.5 (WB)</td><td>WB</td></tr><tr><td rowspan="2">Straumann® Bone Level</td><td>3.3</td><td>NC</td></tr><tr><td>4.1, 4.8</td><td>RC</td></tr><tr><td rowspan="2">Straumann® Tissue Level</td><td>3.3, 4.1, 4.8</td><td>RN</td></tr><tr><td>4.8, 6.5</td><td>WN</td></tr><tr><td rowspan="3">Zimmer Screw-Vent® / Tapered Screw-Vent®</td><td>3.3, 3.7, 4.1</td><td>3.5</td></tr><tr><td>4.7</td><td>4.5</td></tr><tr><td>6.0</td><td>5.7</td></tr></table>	Compatible Third-Party Implant Systems	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	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	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	Keystone PrimaConnex™	3.5	3.5 (SD)	4.1	4.1 (RD)	5.0	5.0 (WD)	MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5	Neodent® GM™ Helix	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	3.0	Neoss	3.5, 4.0, 4.5, 5.0, 5.5	4.1	Nobel Biocare™ NobelActive®	3.0	3.0	3.5	NP	4.3, 5.0	RP	Nobel Biocare™ NobelReplace®	3.5	NP	4.0, 4.3, 5.0	RP	5.0	WP	6.0	6.0	Straumann™ BLX	3.75, 4.0, 4.5 (RB)	RB	5.0, 5.5, 6.5 (WB)	WB	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	<table><tr><th>Platform compatibility</th><th>Platform diameter [mm]</th><th>Implant Body Diameter [mm]</th></tr><tr><td>NobelReplaceNP</td><td>3.5</td><td>3.5</td></tr><tr><td>NobelReplace RP</td><td>4.3</td><td>4.3</td></tr><tr><td>Nobel Replace WP</td><td>5</td><td>5</td></tr><tr><td>NobelReplace 6.0</td><td>6</td><td>6</td></tr><tr><td>Nobel CC 3.0</td><td>3</td><td>3</td></tr><tr><td>NobelCC NP</td><td>3.5</td><td>3.5&3.75</td></tr><tr><td>NobelCC RP</td><td>3.9</td><td>4.3&5</td></tr><tr><td>NobelCC WP</td><td>5.1</td><td>5.5</td></tr><tr><td>Straumann Bone LevelNC</td><td>3.3</td><td>3.3</td></tr><tr><td>Straumam1 Bone Level RC</td><td>4.1&4.8</td><td>4.1&4.8</td></tr><tr><td>Astra Tech 3.5/4.0</td><td>3.5&4</td><td>3.5&4</td></tr><tr><td>Astra Tech 4.5/5.0</td><td>4.5&5</td><td>4.5&5</td></tr><tr><td>Astra Tech EV 3.6</td><td>3.6</td><td>3.6</td></tr><tr><td>Astra Tech EV 4.2</td><td>4.2</td><td>3.6&4.2</td></tr><tr><td>Astra Tech EV 4.8</td><td>4.8</td><td>4.2&4.8</td></tr><tr><td>Astra Tech EV 5.4</td><td>5.4</td><td>5.4</td></tr><tr><td>Branemark NP</td><td>3.5</td><td>3.3</td></tr><tr><td>Branemark RP</td><td>4.1</td><td>3.75, 4&5</td></tr><tr><td>Branemark WP</td><td>5.1</td><td>5&6</td></tr></table>	Platform compatibility	Platform diameter [mm]	Implant Body Diameter [mm]	NobelReplaceNP	3.5	3.5	NobelReplace RP	4.3	4.3	Nobel Replace WP	5	5	NobelReplace 6.0	6	6	Nobel CC 3.0	3	3	NobelCC NP	3.5	3.5&3.75	NobelCC RP	3.9	4.3&5	NobelCC WP	5.1	5.5	Straumann Bone LevelNC	3.3	3.3	Straumam1 Bone Level RC	4.1&4.8	4.1&4.8	Astra Tech 3.5/4.0	3.5&4	3.5&4	Astra Tech 4.5/5.0	4.5&5	4.5&5	Astra Tech EV 3.6	3.6	3.6	Astra Tech EV 4.2	4.2	3.6&4.2	Astra Tech EV 4.8	4.8	4.2&4.8	Astra Tech EV 5.4	5.4	5.4	Branemark NP	3.5	3.3	Branemark RP	4.1	3.75, 4&5	Branemark WP	5.1	5&6
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Comparison of Technological Characteristics

Comparison	Subject Device Preat Abutments Preat Corporation	Primary Predicate Device Preat Abutments Preat Corporation K220823	Reference Device Preat Abutments Preat Corporation K183518	Reference Device Elos Accurate® Customized Abutment Elos Medtech Pinol A/S K222044
FDA Product Code	NHA, PNP	NHA	NHA	NHA, PNP
Regulation	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630
Device Class	Class II	Class II	Class II	Class II
Prescription Device	Yes	Yes	Yes	Yes
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
Reason for Predicate/Reference	Not applicable	Abutment design, abutment parameters, sterilization, biocompatibility	Abutment design, abutment parameters, sterilization, biocompatibility	Validated digital dentistry workflow technology
Abutment Design	Titanium Blank Minimum wall thickness – 0.5 mm. Minimum post height for single-unit restoration – 4.0 mm. Maximum Angle – 30° *. Maximum gingival height – 1.5 mm to 4.5 mm (varies by implant line). <i>*Astra Tech® OsseoSpeed™ Plus (OsseoSpeed™ EV)-compatible 3.6 mm and larger diameter abutments are limited to 0° maximum correction angle.</i>	Titanium Blank Minimum wall thickness – 0.5 mm. Minimum post height for single-unit restoration – 4.0 mm. Maximum Angle – 30° *. Maximum gingival height – 2.0 mm to 4.5 mm (varies by implant line). <i>*Astra Tech® OsseoSpeed™ Plus (OsseoSpeed™ EV)-compatible 3.6 mm and larger diameter abutments are limited to 0° maximum correction angle.</i>	Titanium Blank Minimum wall thickness – 0.5 mm. Minimum post height for single-unit restoration – 4.0 mm. Maximum Angle – 30°. Maximum gingival height – 1.5 mm to 2.65 mm (varies by implant line).	Titanium Blank Minimum wall thickness – 0.4 to 0.5 mm (varies by implant line). Minimum post height for single-unit restoration – 4.0 mm. Maximum Angle – 20° or 30° (varies by implant line). Maximum gingival height – 5 mm.
Material (Abutment and Screw)	Ti-6AL-4V Alloy	Ti-6AL-4V Alloy	Ti-6AL-4V Alloy	Steam sterilization – End User
Abutment/Implant Interface	Internal Connection	Internal Connection	Internal Connection	Internal Connection
Prosthesis Attachment	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained	Cement-retained Screw-retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Implant Platform Diameter (mm)	2.9-6.0	2.9-5.4	3.0-6.0	3.0-6.0
Design Workflow	Intra-Oral or Desktop Dental Scanner 3Shape Abutment Designer exocad AbutmentCAD	Validated Milling Center	Validated Milling Center	3Shape scanner (3Shape A/S), 3Shape Abutment Designer Software (3Shape A/S) – K151455
Manufacturing Workflow	Digital Dental – Titan Hyperdent	Validated Milling Center	Validated Milling Center	CORITEC milling unit (imes-icore)
Sterilization Method	Steam sterilization – End User	Steam sterilization – End User	Steam sterilization – End User	Steam sterilization – End User