



February 10, 2020

Elos Medtech Pinol A/S
% Floyd Larson
President
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K191919
Trade/Device Name: Elos Accurate® Hybrid Base
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 6, 2020
Received: January 7, 2020

Dear Floyd Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

Sincerely,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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)

K191919

Device Name

Elos Accurate® Hybrid Base

Indications for Use (Describe)

The Elos Accurate® Hybrid Base™ is intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Hybrid Base™ is used as an interface between a dental implant and a zirconia superstructure and will be attached to the implant using the included prosthetic screw and attached to the zirconia superstructure by cementing.

The Elos Accurate® Hybrid Base™ is compatible with the implant systems listed in Table 1.

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Nobel Replace NP	3.5	3.5
Nobel Replace RP	4.3	4.3
Nobel Replace WP	5	5
Nobel Replace 6.0	6	6
Nobel CC 3.0	3	3
Nobel CC NP	3.5	3.5 & 3.75
Nobel CC RP	3.9	4.3 & 5
Nobel CC WP	5.1	5.5
Straumann Bone Level NC	3.3	3.3
Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8
Astra Tech 3.0	3	3
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 3.0	3	3
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

All digitally designed zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are only intended to be sent and manufactured at an FDA registered Elos Medtech approved milling facility.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

K191919

Elos Medtech Pinol A/S Elos

Accurate® Hybrid Base™

February 10, 2020

ADMINISTRATIVE INFORMATION

Manufacturer Name	Elos Medtech Pinol A/S Engvej 33 DK-3330 Gørløse, Denmark Telephone +45 48 21 64 69
Official Contact	Tina Friis Poulsen, Head of Compliance
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin A. Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: flarson@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Elos Accurate® Hybrid Base™
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 Division	DHT1B: Division of Dental Devices

PREDICATE DEVICE INFORMATION

Primary Predicate
K173908, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices

K151621, BioHorizons CAD/CAM Abutments, BioHorizons Implant Systems, Inc.
K171799, Elos Accurate® Customized Abutment, Elos Medtech Pinol A/S
K183518, Preat Abutments, Preat Corporation
K080396, OsseoSpeed Narrow, Dentsply Sirona
K053384, Fixture MicroThread OsseoSpeed, Dentsply Sirona
K120414, OsseoSpeed Plus, Dentsply Sirona
K102436, NobelActive 3.0, Nobel Biocare AB

K071370, NobelActive Internal Connection Implant, Nobel Biocare AB
 K133731, NobelActive Wide Platform (WP), Nobel Biocare AB
 K023113, Replace TiUnite Endoessous Implant, Nobel Biocare AB
 K062129, P.0004 Implants (Straumann Dental Implant System), Institut Straumann
 K130436, Multilink Hybrid Abutment Cement, Ivoclar Vivadent AG

INDICATIONS FOR USE

The Elos Accurate® Hybrid Base™ is intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Hybrid Base™ is used as an interface between a dental implant and a zirconia superstructure and will be attached to the implant using the included prosthetic screw and attached to the zirconia superstructure by cementing.

The Elos Accurate® Hybrid Base™ is compatible with the implant systems listed in Table 1.

Table 1.

Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]
Nobel Replace NP	3.5	3.5
Nobel Replace RP	4.3	4.3
Nobel Replace WP	5	5
Nobel Replace 6.0	6	6
Nobel CC 3.0	3	3
Nobel CC NP	3.5	3.5 & 3.75
Nobel CC RP	3.9	4.3 & 5
Nobel CC WP	5.1	5.5
Straumann Bone Level NC	3.3	3.3
Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8
Astra Tech 3.0	3	3
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 3.0	3	3
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

All digitally designed zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are only intended to be sent and manufactured at an FDA registered Elos Medtech approved milling facility.

DEVICE DESCRIPTION

The Elos Accurate Hybrid Base is a titanium base designed to interface with a dental implant and to support a patient-specific ceramic superstructure or a multi-unit direct restoration cemented to the base. The base and the superstructure form a patient-specific abutment that will support a definitive restoration, either a single crown or a multi-unit restoration. The Elos Accurate Hybrid Base Engaging is intended for single-unit restorations and Elos Accurate Hybrid Base Non-engaging is intended for multi-unit restorations. Alternatively, a definitive multi-unit restoration may be cemented directly to the Elos Accurate Hybrid Base.

Manufacture of the final finished device will be at an Elos Medtech-approved milling facility that is registered with FDA as a medical device manufacturer and is qualified as a contract manufacturer to Elos Medtech.

This submission includes a two-piece abutment (titanium base and zirconia superstructure) and abutment screws compatible with OEM implants from Dentsply Implants (Astra Tech TX, Astra Tech EV), Nobel Biocare (Nobel Active/Conical Connection and Nobel Replace) and Institut Straumann (Straumann Bone Level NC and RC).

Abutments compatible with Astra Tech implants are available in engaging (anti-rotational) designs, and all others are available in both engaging and non-engaging designs.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence include: biocompatibility evaluation and confirmatory cytotoxicity testing according to ISO 10993-5 *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*, and dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*. No clinical data were included in this submission.

Substantial equivalence with regard to compatibility with OEM components is supported by engineering and dimensional analysis of OEM implant bodies, OEM abutments and OEM abutment fixation screws to confirm compatibility.

Substantial equivalence with regard to mechanical performance is supported by dynamic testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*.

The coatings used on selected screws are identical to coatings on previously cleared devices. The Medicarb coating is identical to the Medicarb (DLC) coating on reference device K171799 and the Nobel DLC coating is identical to the DLC coating on compatible device K071370. Sterilization validation of the reprocessing instructions were conducted in accordance to ISO 17665-1 and ISO 17665-2.

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 a determination of substantial equivalence because these differences are related to the compatible OEM implant designs or are mitigated by the mechanical performance testing.

EQUIVALENCE TO MARKETED DEVICE

Overall, the subject device has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

The basis for the belief of Elos Medtech Pinol A/S that the subject device is substantially equivalent to the predicate devices is summarized in the following *Table of Substantial Equivalence*.

Table of Substantial Equivalence – Indications for Use Statement

Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device																																																																																																																																																																																																									
<p>Elos Accurate® Hybrid Base™</p> <p>Elos Medtech Pinol A/S</p>	<p>K173908 DESS Dental Smart Solutions</p> <p>Terrats Medical SL</p>	<p>K151621 BioHorizons CAD/CAM Abutments</p> <p>BioHorizons Implant Systems, Inc.</p>	<p>K171799 Elos Accurate® Customized Abutment,</p> <p>Elos Medtech Pinol A/S</p>	<p>K183518 Preat Abutments</p> <p>Preat Corporation</p>																																																																																																																																																																																																									
<p>The Elos Accurate® Hybrid Base™ is intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Hybrid Base™ is used as an interface between a dental implant and a zirconia superstructure and will be attached to the implant using the included prosthetic screw and attached to the zirconia superstructure by cementing.</p> <p>The Elos Accurate® Hybrid Base™ is compatible with the implant systems listed in Table 1.</p> <p>Table 1.</p> <table border="1" data-bbox="100 597 449 1032"> <thead> <tr> <th>Implant Platform compatibility</th> <th>Platform diameter [mm]</th> <th>Implant Body diameter [mm]</th> </tr> </thead> <tbody> <tr><td>Nobel Replace NP</td><td>3.5</td><td>3.5</td></tr> <tr><td>Nobel Replace 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>Nobel Replace 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>Nobel CC NP</td><td>3.5</td><td>3.5 & 3.75</td></tr> <tr><td>Nobel CC RP</td><td>3.9</td><td>4.3 & 5</td></tr> <tr><td>Nobel CC WP</td><td>5.1</td><td>5.5</td></tr> <tr><td>Straumann Bone Level NC</td><td>3.3</td><td>3.3</td></tr> <tr><td>Straumann Bone Level RC</td><td>4.1 & 4.8</td><td>4.1 & 4.8</td></tr> <tr><td>Astra Tech 3.0</td><td>3</td><td>3</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 3.0</td><td>3</td><td>3</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> </tbody> </table> <p>All digitally designed zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are only intended to be sent and manufactured at an FDA registered Elos Medtech approved milling facility.</p>	Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]	Nobel Replace NP	3.5	3.5	Nobel Replace RP	4.3	4.3	Nobel Replace WP	5	5	Nobel Replace 6.0	6	6	Nobel CC 3.0	3	3	Nobel CC NP	3.5	3.5 & 3.75	Nobel CC RP	3.9	4.3 & 5	Nobel CC WP	5.1	5.5	Straumann Bone Level NC	3.3	3.3	Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8	Astra Tech 3.0	3	3	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 3.0	3	3	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	<p>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.</p> <p>All digitally designed custom abutments for use with Aurum™ Abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture.</p> <p>Compatible Implant Systems</p> <table border="1" data-bbox="520 561 898 928"> <thead> <tr> <th>Implant System Compatibility</th> <th>Implant Body</th> <th>Implant Platform</th> </tr> </thead> <tbody> <tr><td>3i Certain®</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr> <tr><td>3i OSSEOTITE®</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr> <tr><td>OsseoSpeed™</td><td>3.5, 4.0, 5.0</td><td>3.5/4.0, 4.5/5.0</td></tr> <tr><td>FRIDENT XiVE</td><td>3.4, 3.8, 4.5</td><td>3.4, 3.8, 4.5</td></tr> <tr><td>NobelActive®</td><td>3.5, 4.3, 5.0</td><td>NP, RP</td></tr> <tr><td>NobelReplace Conical</td><td>3.5, 4.3, 5.0</td><td>NP, RP</td></tr> <tr><td>Nobel Replace Trilobe</td><td>3.5, 4.3, 5.0</td><td>NP, RP, WP</td></tr> <tr><td>Brånemark</td><td>3.5, 3.75/4.0, 5.0</td><td>NP, RP, WP</td></tr> <tr><td>Straumann® Bone Level</td><td>3.3, 4.1, 4.8</td><td>NC, RC</td></tr> <tr><td>Straumann® Tissue Level</td><td>3.3, 4.1, 4.8</td><td>RN, WN</td></tr> <tr><td>Tapered Screw-Vent®</td><td>3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr> </tbody> </table> <p>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.</p>	Implant System Compatibility	Implant Body	Implant Platform	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	FRIDENT 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	<p>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.</p> <p>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.</p>	<p>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.</p> <p>The Elos Accurate® Customized Abutments are compatible with the following implant systems:</p> <table border="1" data-bbox="1163 561 1524 708"> <thead> <tr> <th>Ref. No.</th> <th>Platform compatibility</th> <th>Implant diameter</th> </tr> </thead> <tbody> <tr><td>AB-BRA411213-US</td><td>Nobel Biocare® / Brånemark® RP</td><td>3.75 mm & 4 mm</td></tr> <tr><td>AB-BRA351213-US</td><td>Nobel Biocare® / Brånemark® RP</td><td>3.3 mm</td></tr> <tr><td>AB-BRA511213-US</td><td>Nobel Biocare® / Brånemark® RP</td><td>5 mm</td></tr> </tbody> </table> <p>All digitally designed Elos Accurate® Customized Abutments are intended to be manufactured at an Elos Medtech approved milling facility.</p>	Ref. No.	Platform compatibility	Implant diameter	AB-BRA411213-US	Nobel Biocare® / Brånemark® RP	3.75 mm & 4 mm	AB-BRA351213-US	Nobel Biocare® / Brånemark® RP	3.3 mm	AB-BRA511213-US	Nobel Biocare® / Brånemark® RP	5 mm	<p>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.</p> <p>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.</p> <p>Compatible Implant Systems</p> <table border="1" data-bbox="1539 571 2045 1318"> <thead> <tr> <th>Compatible Implant System</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 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> </tbody> </table>	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	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	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
Implant Platform compatibility	Platform diameter [mm]	Implant Body diameter [mm]																																																																																																																																																																																																											
Nobel Replace NP	3.5	3.5																																																																																																																																																																																																											
Nobel Replace RP	4.3	4.3																																																																																																																																																																																																											
Nobel Replace WP	5	5																																																																																																																																																																																																											
Nobel Replace 6.0	6	6																																																																																																																																																																																																											
Nobel CC 3.0	3	3																																																																																																																																																																																																											
Nobel CC NP	3.5	3.5 & 3.75																																																																																																																																																																																																											
Nobel CC RP	3.9	4.3 & 5																																																																																																																																																																																																											
Nobel CC WP	5.1	5.5																																																																																																																																																																																																											
Straumann Bone Level NC	3.3	3.3																																																																																																																																																																																																											
Straumann Bone Level RC	4.1 & 4.8	4.1 & 4.8																																																																																																																																																																																																											
Astra Tech 3.0	3	3																																																																																																																																																																																																											
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 3.0	3	3																																																																																																																																																																																																											
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																																																																																																																																																																																																											
Implant System Compatibility	Implant Body	Implant Platform																																																																																																																																																																																																											
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																																																																																																																																																																																																											
FRIDENT 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																																																																																																																																																																																																											
Ref. No.	Platform compatibility	Implant diameter																																																																																																																																																																																																											
AB-BRA411213-US	Nobel Biocare® / Brånemark® RP	3.75 mm & 4 mm																																																																																																																																																																																																											
AB-BRA351213-US	Nobel Biocare® / Brånemark® RP	3.3 mm																																																																																																																																																																																																											
AB-BRA511213-US	Nobel Biocare® / Brånemark® RP	5 mm																																																																																																																																																																																																											
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																																																																																																																																																																																																											
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																																																																																																																																																																																																											
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																																																																																																																																																																																																											

Table of Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate	Reference Device	Reference Device	Reference Device
	Elos Accurate® Hybrid Base™ Elos Medtech Pinol A/S	K173908 DESS Dental Smart Solutions Terrats Medical SL	K151621 BioHorizons CAD/CAM Abutments BioHorizons Implant Systems, Inc.	K171799 Elos Accurate® Customized Abutment Elos Medtech Pinol A/S	K183518 Preat Abutments Preat Corporation
Intended Use	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function
Reason for Predicate/Reference	Not applicable	Abutment design	Abutment design	Medicarb (DLC) coating on screws	Performance testing data
Abutment Designs	Titanium Base Engaging	Titanium Base Engaging	Titanium Base Engaging		Titanium Base Engaging
	Titanium Base Non-Engaging	Titanium Base Non-Engaging	Titanium Base Non-Engaging		Titanium Base Non-Engaging
			Others	Titanium Blank Engaging	Others
Prosthesis Attachment	Cement-retained	Cement-retained	Cement-retained	Cement-retained	Cement-retained Screw retained
Restoration	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit	Single-unit Multi-unit
Abutment/Implant Platform Diameter (mm)	3.0 – 6.5	3.3 – 6.5	3.0 – 5.7	3.5 – 5.1	3.0 – 5.7
Abutment Angle	20° maximum	Straight (0°)	20° maximum	20° maximum	30° maximum
Abutment/ Implant Interface	Internal connection	Internal connection; External connection	Internal connection	Internal connection	Internal connection
Materials					
Abutment	Ti-6Al-4V alloy Zirconia according to ISO 13356	Ti-6Al-4V alloy Zirconia according to ISO 13356	Ti-6Al-4V alloy Zirconia according to ISO 13356	Ti-6Al-4V alloy	Ti-6Al-4V alloy Zirconia according to ISO 13356
Screw	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy
Surface	Anodized, non-anodized, Medicarb coating on screw	Anodized	Anodized	Non-anodized, Medicarb coating on screw	Non-anodized