August 4, 2021

Terrats Medical SL
℅ Floyd Larson
President
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K203464
Trade/Device Name: DESS Dental Smart Solutions
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 16, 2021
Received: July 19, 2021

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203464

Device Name
DESS Dental Smart Solutions

Indications for Use *(Describe)*

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 C-Base abutments are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems

Compatible Implant System	Implant Body Diameter, mm	Implant Platform
Ankylos C/X	3.5, 4.5, 5.5	2.52 mm
Astra Tech EV	3.6	2.9 mm
	4.2	3.5 mm
	4.8	4.1 mm
Astra Tech OsseoSpeed™	3.5/4.0	3.5/4.0 mm
	4.5/5.0	4.5/5.0 mm
Biomet 3i Certain®	3.25	3.45 mm
	4.0	4.1 mm
	5.0	5.0 mm
Biomet 3i OSSEOTITE®	3.25	3.4 mm
	3.75, 4.0	4.1 mm
	5.0	5.0 mm
FRIADENT XiVE®	3.4	3.4 mm
	3.8	3.8 mm
	4.5	4.5 mm
	5.5	5.5 mm
NobelActive®, NobelReplace/NobelParallel Conical	3.5	NP (3.5 mm)
	4.3, 5.0	RP (3.9 mm)
	5.5	WP (5.1 mm)
NobelReplace® (Internal tri-channel)	3.5	NP (3.5 mm)
	4.3	RP (4.3 mm)
	5.0	WP (5.0 mm)
	6.0	6.0 (6.0 mm)
Nobel Brånemark System®	3.3	NP (3.5 mm)
	3.75, 4.0	RP (4.1 mm)
Osstem TS	4.0, 4.5, 5.0, 6.0, 7.0	Regular (3.35 mm)
Straumann® Bone Level	3.3	NC (3.3 mm)
	4.1/4.8	RC (4.1/4.8 mm)
Straumann® Tissue Level	3.3, 4.1, 4.8	RN (4.8 mm)
	4.8	WN (6.5 mm)
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5 mm
	4.7	4.5 mm
	6.0	5.7 mm

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
PRAStaff@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
Terrats Medical SL
DESS Dental Smart Solutions

K203464

August 4, 2021

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda, 75-99 Barberà del Vallès Barcelona, Spain Telephone +34 935 646 006 Fax +34 935 646 006
Official Contact	Roger Terrats, COO
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin 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	DESS Dental Smart Solutions
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 Device
K191986, DESS Dental Smart Solutions, Terrats Medical SL

Additional Predicate Device
K170588, DESS Dental Smart Solutions, Terrats Medical SL

INDICATIONS FOR USE STATEMENT

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 C-Base abutments are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems

Compatible Implant System	Implant Body Diameter, mm	Implant Platform
Ankylos C/X	3.5, 4.5, 5.5	2.52 mm
Astra Tech EV	3.6	2.9 mm
	4.2	3.5 mm
	4.8	4.1 mm
Astra Tech OsseoSpeed™	3.5/4.0	3.5/4.0 mm
	4.5/5.0	4.5/5.0 mm
Biomet 3i Certain®	3.25	3.45 mm
	4.0	4.1 mm
	5.0	5.0 mm
Biomet 3i OSSEOTITE®	3.25	3.4 mm
	3.75, 4.0	4.1 mm
	5.0	5.0 mm
FRIADENT XiVE®	3.4	3.4 mm
	3.8	3.8 mm
	4.5	4.5 mm
	5.5	5.5 mm
NobelActive®, NobelReplace/NobelParallel Conical	3.5	NP (3.5 mm)
	4.3, 5.0	RP (3.9 mm)
	5.5	WP (5.1 mm)
NobelReplace® (Internal tri-channel)	3.5	NP (3.5 mm)
	4.3	RP (4.3 mm)
	5.0	WP (5.0 mm)
	6.0	6.0 (6.0 mm)
Nobel Brånemark System®	3.3	NP (3.5 mm)
	3.75, 4.0	RP (4.1 mm)
Osstem TS	4.0, 4.5, 5.0, 6.0, 7.0	Regular (3.35 mm)
Straumann® Bone Level	3.3	NC (3.3 mm)
	4.1/4.8	RC (4.1/4.8 mm)
Straumann® Tissue Level	3.3, 4.1, 4.8	RN (4.8 mm)
	4.8	WN (6.5 mm)
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5 mm
	4.7	4.5 mm
	6.0	5.7 mm

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the DESS Dental Smart Solutions abutment system cleared under K170588 and K191986 to add an additional series of titanium base components for previously cleared OEM implant platform compatibilities. The new components, referred to as C-Base engaging and C-Base non-engaging abutments, are available in a range of abutment gingival heights and abutment platform diameters. This submission includes abutments compatible with 33 implant platforms from 13 implant systems. All implant compatibilities have been cleared in previous Terrats Medical submissions. No new implant compatibilities are added in this submission. Screws used with the subject device C-Base abutments were cleared previously, with the exception of two screws added in this submission. The two screws added in this submission are specific to the Zimmer Screw Vent® / Tapered Screw-Vent® Implants and Ankylos C/X Implants and are not for use with any other previously cleared implant bodies.

The subject device DESS Dental Smart Solutions C-Base abutments are similar to TiBase Abutments cleared in K170588 and K191986. C-Base abutments are two-piece abutments designed to support a custom CAD/CAM zirconia superstructure on which a single-unit or multi-unit restoration may be placed. The ceramic superstructure produced through CAD/CAM is the second part of the two-piece abutment. The C-Base also may support a ceramic hybrid abutment (direct restoration) in which the crown is included in the design of the zirconia superstructure. They are available either in designs that engage with the anti-rotational feature of the implant or in non-engaging designs for multi-unit restorations. The C-Base post is 4.7 mm high. The gingival height of the abutment (distance from implant platform to abutment platform) ranges from 0.3 mm to 3.0 mm. All patient-specific custom abutment fabrication is by prescription on the order of the clinician. C-Base abutments are made of titanium alloy (Ti-6Al-4V) with anodization and a SelectGrip® surface, described below. When used for a direct crown, a POM burn-out sleeve, an exempt laboratory component that is not a subject of this submission, is available for laboratory fabrication of the prosthesis.

When the C-Base abutment is used with a CAD/CAM zirconia superstructure, or for a direct restoration, design parameters are identical to those cleared in K191986 and in K170588, except that the minimum post height for the subject device is 4.7 mm. The superstructure or direct restoration design parameters are:

Minimum wall thickness – 0.4 mm
Minimum post height for single-unit loading – 4.7 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
Zirconia superstructures and direct restorations are not intended for angulation correction.

Manufacture of the CAD/CAM zirconia superstructure is to be performed at a Terrats Medical validated milling center, defined as a facility that is registered with FDA as a manufacturer or contract manufacturer.

Each abutment is supplied with the appropriate abutment screw for attachment to the corresponding implant. DESS Dental Smart Solutions screws are designed to attach the abutment or restoration to the implant. With the exception of two new subject device screws, all screws were cleared in previous Terrats Medical submissions. As discussed above, the two screws added in this submission are specific to the Zimmer Screw Vent® / Tapered Screw-Vent® Implants and Ankylos C/X Implants and are not for use with any other previously cleared implant bodies.

All subject device abutments and subject device screws are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra*

Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). Zirconia superstructures for C-Base abutments are made of Y-TZP conforming to ISO 13356 *Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP).*

Abutments are colored gold by an anodization process in which the abutment is submerged in an electrolytic solution and exposed to an electric current to achieve the gold color. They also are treated with the SelectGrip® surface to improve adhesion of the cement that is used to attach the superstructure or restoration to the C-Base abutment. The gold anodized surface treatment is identical to that cleared in K191986 and the SelectGrip surface treatment is identical to that cleared in K191986 and K170588. All the subject device components are manufactured from the same materials, are treated with the same surface treatments and are manufactured in the same facilities using the same manufacturing processes as used for the previously cleared predicate devices in K191986 and K170588.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1 and ISO 17665-2 referenced from the primary predicate device and the sponsor's additional predicate device; biocompatibility according to ISO 10993-5 and ISO 10993-12 referenced from the primary predicate device and the sponsor's additional predicate device; and reverse engineering analysis of OEM implant bodies, OEM abutment, and OEM abutment screws to confirm compatibility, referenced from the primary predicate device and the additional predicate device. The two screws added in this submission are specific to the Zimmer Screw Vent® / Tapered Screw-Vent® Implants and Ankylos C/X Implants. Because the minor differences between the designs of these two subject device screws and corresponding screws cleared in K170588 and K191986 are not related to implant compatibility, no new OEM analysis was needed. 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 TiBase abutments of the primary predicate device and the sponsor's additional predicate device listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the additional predicate device.

Subject device abutments are substantially equivalent in intended use to the TiBase abutments of the primary predicate device cleared in K191968 and the additional predicate device cleared in K170588. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation. The Indications for Use Statement (IFUS) for the subject device is identical to that of the primary predicate K191986 and the additional predicate K170588, except for the specific name of the subject device and the list of compatible OEM implants.

All subject device abutments are similar in design and are identical in materials and technological characteristics to the TiBase abutments of the primary predicate K191986. All are titanium base abutments intended to be completed by attaching a zirconia superstructure fabricated from Y-TZP conforming to ISO 13356 *Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)* that is manufactured at a validated milling center – a facility that is registered with FDA as a manufacturer and is approved by Terrats Medical as a contract manufacturer.

The only differences between the subject devices and the TiBase abutments of the primary predicate device are slight dimensional differences in the portion of the abutment to which the zirconia superstructure is cemented. These differences include a slightly greater post height for the subject devices (4.7 mm vs. 4.2 mm), the addition of retention grooves to the post of the subject device and a slight taper in the coronal portion of the post of the subject device. These differences are accommodated by corresponding differences in the design of the zirconia superstructure. These differences do not affect the worst-case design parameters of the corresponding superstructures and do not have any effect on substantial equivalence.

All implant compatibilities for subject devices are included among those for primary predicate devices in K191986 and for additional predicate devices in K170588. Because compatibility has been demonstrated in these predicate submissions, this submission does not include compatibility analysis.

The SelectGrip® surface on subject C-Base abutments is identical to the SelectGrip surface on equivalent abutments cleared in the primary predicate K191986 and in the additional predicate K170588.

The gold anodized surface on subject C-Base abutments is identical to the anodized surface on Aurum Abutments of the primary predicate K191986.

The two subject device screws are substantially equivalent in design, materials, and technological characteristics to those cleared in the primary predicate K191986 and additional predicate K170588. The new screw designs incorporate only changes related to the new geometries of the subject abutments and are not related to any mating features with the OEM devices.

Digital files for all CAD/CAM superstructures must be sent to a validated milling center for manufacture. DESS C-Base abutments are for fabrication of straight custom abutments only.

The subject device is to be sterilized by the end-user, the same as primary predicate device K191986 and additional predicate device K170588.

All the subject device components are manufactured from the same materials and in the same facilities using the same manufacturing processes as used for the Terrats Medical components previously cleared in K191986 and K170588. Therefore, no new biocompatibility testing has been performed, as the subject device is substantially equivalent to the predicate devices in K191986 and K170588 with regard to materials and processing.

Minor differences in the designs, dimensions or sizes among the subject device, the primary predicate device, and the additional predicate device do not affect substantial equivalence. These minor differences do not impact substantial equivalence because the only differences are in the portion of the abutment to which the CAD/CAM zirconia superstructure is attached.

CONCLUSION

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

Table of Substantial Equivalence – Indications for Use Statement

<table>
<tr><th>Subject Device</th><th>Indications for Use Statement</th></tr>
<tr><td>DESS Dental Smart Solutions
Terrats Medical SL</td><td>
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 C-Base abutments are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems
<table>
<tr><th>Compatible Implant System</th><th>Implant Body Diameter, mm</th><th>Implant Platform</th></tr>
<tr><td>Ankylos C/X</td><td>3.5, 4.5, 5.5</td><td>2.52 mm</td></tr>
<tr><td rowspan="3">Astra Tech EV</td><td>3.6</td><td>2.9 mm</td></tr>
<tr><td>4.2</td><td>3.5 mm</td></tr>
<tr><td>4.8</td><td>4.1 mm</td></tr>
<tr><td rowspan="2">Astra Tech OsseoSpeed™</td><td>3.5/4.0</td><td>3.5/4.0 mm</td></tr>
<tr><td>4.5/5.0</td><td>4.5/5.0 mm</td></tr>
<tr><td rowspan="3">Biomet 3i Certain®</td><td>3.25</td><td>3.45 mm</td></tr>
<tr><td>4.0</td><td>4.1 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="3">Biomet 3i OSSEOTITE®</td><td>3.25</td><td>3.4 mm</td></tr>
<tr><td>3.75, 4.0</td><td>4.1 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="4">FRIADENT XiVE®</td><td>3.4</td><td>3.4 mm</td></tr>
<tr><td>3.8</td><td>3.8 mm</td></tr>
<tr><td>4.5</td><td>4.5 mm</td></tr>
<tr><td>5.5</td><td>5.5 mm</td></tr>
<tr><td rowspan="3">NobelActive®,
NobelReplace/NobelParallel Conical</td><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3, 5.0</td><td>RP (3.9 mm)</td></tr>
<tr><td>5.5</td><td>WP (5.1 mm)</td></tr>
<tr><td rowspan="4">NobelReplace®
(Internal tri-channel)</td><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3</td><td>RP (4.3 mm)</td></tr>
<tr><td>5.0</td><td>WP (5.0 mm)</td></tr>
<tr><td>6.0</td><td>6.0 (6.0 mm)</td></tr>
<tr><td rowspan="2">Nobel Brånemark System®</td><td>3.3</td><td>NP (3.5 mm)</td></tr>
<tr><td>3.75, 4.0</td><td>RP (4.1 mm)</td></tr>
<tr><td>Osstem TS</td><td>4.0, 4.5, 5.0, 6.0, 7.0</td><td>Regular (3.35 mm)</td></tr>
<tr><td rowspan="2">Straumann® Bone Level</td><td>3.3</td><td>NC (3.3 mm)</td></tr>
<tr><td>4.1/4.8</td><td>RC (4.1/4.8 mm)</td></tr>
<tr><td rowspan="2">Straumann® Tissue Level</td><td>3.3, 4.1, 4.8</td><td>RN (4.8 mm)</td></tr>
<tr><td>4.8</td><td>WN (6.5 mm)</td></tr>
<tr><td rowspan="3">Zimmer Screw Vent®/
Tapered Screw-Vent®</td><td>3.3, 3.7, 4.1</td><td>3.5 mm</td></tr>
<tr><td>4.7</td><td>4.5 mm</td></tr>
<tr><td>6.0</td><td>5.7 mm</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Primary Predicate Device</th><th>Indications for Use Statement</th></tr>
<tr><td>191986,
DESS Dental Smart Solutions
Terrats Medical SL</td><td>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 abutments or Pre-milled (Blank) abutments are to be sent to a Terrats Medical validated milling center for manufacture.
Compatible Implant Systems
<table>
<tr><th>Compatible Implant System</th><th>Implant Body Diameter, mm</th><th>Implant Platform</th></tr>
<tr><td>Ankylos C/X</td><td>3.5, 4.5, 5.5</td><td>2.52 mm</td></tr>
<tr><td rowspan="3">Astra Tech EV</td><td>3.6</td><td>2.9 mm</td></tr>
<tr><td>4.2</td><td>3.5 mm</td></tr>
<tr><td>4.8</td><td>4.1 mm</td></tr>
<tr><td rowspan="3">Astra Tech OsseoSpeed™</td><td>3.0</td><td>3.0 mm</td></tr>
<tr><td>3.5/4.0</td><td>3.5/4.0 mm</td></tr>
<tr><td>4.5/5.0</td><td>4.5/5.0 mm</td></tr>
<tr><td rowspan="3">Biomet 3i Certain®</td><td>3.25</td><td>3.45 mm</td></tr>
<tr><td>4.0</td><td>4.1 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="3">Biomet 3i OSSEOTITE®</td><td>3.25</td><td>3.4 mm</td></tr>
<tr><td>3.75, 4.0</td><td>4.1 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="4">Camlog</td><td>3.3</td><td>3.3 mm</td></tr>
<tr><td>3.8</td><td>3.8 mm</td></tr>
<tr><td>4.3</td><td>4.3 mm</td></tr>
<tr><td>5.0</td><td>5.0 mm</td></tr>
<tr><td rowspan="4">FRIADENT XiVE®</td><td>3.4</td><td>3.4 mm</td></tr>
<tr><td>3.8</td><td>3.8 mm</td></tr>
<tr><td>4.5</td><td>4.5 mm</td></tr>
<tr><td>5.5</td><td>5.5 mm</td></tr>
<tr><td>MegaGen AnyRidge</td><td>3.5, 4.0, 4.5, 5.0, 5.5</td><td>3.5 mm</td></tr>
<tr><td rowspan="4">NobelActive®,
NobelParallel Conical</td><td>3.0</td><td>3.0 (3.0 mm)</td></tr>
<tr><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3, 5.0</td><td>RP (3.9 mm)</td></tr>
<tr><td>5.5</td><td>WP (5.1 mm)</td></tr>
<tr><td rowspan="4">NobelReplace® Trilobe</td><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3</td><td>RP (4.3 mm)</td></tr>
<tr><td>5.0</td><td>WP (5.0 mm)</td></tr>
<tr><td>6.0</td><td>6.0 (6.0 mm)</td></tr>
<tr><td rowspan="3">Nobel Brånemark System®</td><td>3.3</td><td>NP (3.5 mm)</td></tr>
<tr><td>3.75, 4.0</td><td>RP (4.1 mm)</td></tr>
<tr><td>5.0</td><td>WP (5.1 mm)</td></tr>
<tr><td rowspan="2">Osstem TS</td><td>3.5</td><td>Mini (2.8 mm)</td></tr>
<tr><td>4.0, 4.5, 5.0, 6.0, 7.0</td><td>Regular (3.35 mm)</td></tr>
<tr><td rowspan="2">Straumann® Bone Level</td><td>3.3</td><td>NC (3.3 mm)</td></tr>
<tr><td>4.1/4.8</td><td>RC (4.1/4.8 mm)</td></tr>
<tr><td rowspan="3">Straumann® Tissue Level</td><td>3.3</td><td>NNC (3.5 mm)</td></tr>
<tr><td>3.3, 4.1, 4.8</td><td>RN (4.8 mm)</td></tr>
<tr><td>4.8</td><td>WN (6.5 mm)</td></tr>
<tr><td rowspan="3">Zimmer Screw Vent®/ Tapered Screw-Vent®</td><td>3.3, 3.7, 4.1</td><td>3.5 mm</td></tr>
<tr><td>4.7</td><td>4.5 mm</td></tr>
<tr><td>6.0</td><td>5.7 mm</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Additional Predicate Device</th><th>Indications for Use Statement</th></tr>
<tr><td>K170588, DESS Dental Smart Solutions Terrats Medical SL</td><td>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
<table><tr><th>Implant System Compatibility</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr><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>FRIADENT 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></table></td></tr>
</table>

Table of Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Additional Predicate Device
	DESS Dental Smart Solutions Terrats Medical SL	K191986 DESS Dental Smart Solutions Terrats Medical SL	K170588 DESS Dental Smart Solutions Terrats Medical SL
Design			
Abutment Design(s)	CAD/CAM Bases	Healing, Temporary, Straight, Multi-unit, Locator-type, CAD/CAM Bases, CAD/CAM Blanks,	Healing, Temporary, Straight, Multi-unit, Locator-type, CAD/CAM Bases, CAD/CAM Blanks,
Prosthesis Attachment	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
Abutment/Implant Platform Diameter, mm	2.52 – 6.5	2.52 – 6.5	3.3 – 6.5
TiBase Post Height, mm	4.7	4.2	4.2
TiBase Post Diameter	3.0	3.5	3.5
Abutment/ Implant Interface	Internal, External	Internal, External	Internal, External
Final TiBase Abutment Design			
Minimum Wall thickness, mm	0.4	0.4	0.4
Minimum Post Height (Single Unit), mm	4.7	4.0	4.2
Minimum Gingival Height, mm	0.5		
Maximum Gingival Height, mm	6.0	6.0	6.0
TiBase Abutment Angles	Straight (0°)	Straight (0°)	Straight (0°)
Material			
Abutments	Ti-6Al-4V ELI, Zirconia (Y-TZP)	Ti-6Al-4V ELI, Co-Cr-Mo Alloy, Zirconia (Y-TZP)	Ti-6Al-4V ELI, Zirconia (Y-TZP)
Abutment Surface Treatment	Gold anodized, SelectGrip	Gold anodized (DESS Aurum), SelectGrip (Ti Base – Interface)	SelectGrip
Screws	Ti-6Al-4V ELI Without coating	Ti-6AlI-4V ELI With or without DLC coating	Ti-6Al-4V ELI With or without DLC coating