October 26, 2022

Terrats Medical SL
% Kevin Thomas
Vice President & Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K222269
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 28, 2022
Received: July 28, 2022

Dear Kevin Thomas:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/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

Indications for Use

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

510(k) Number *(if known)*
K222269

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 DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems

Compatible Implant System (Connection)	**Implant Body Diameter, mm**	**Implant Platform**
PRIMA CONNEX (Internal TiLobe, Tapered & Straight)	3.3, 3.5	3.5
	4.0, 4.1	4.1
	5.0	5.0
GENESIS (Internal TiLobe)	3.5, 3.8	3.5/3.8
	4.5	4.5
	5.5, 6.5	5.5/6.5
MOLARIS TILOBEMAXX (Internal TiLobe)	7	5.7
	8	6.5
	9	7.5
MOLARIS I-HEXMRT (Internal Hex)	7	5.7
	8	6.5
	9	7.5
PALTOP ADVANCED CLASSIC (Internal Hex)	3.25	NP (3.25)
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)
PALTOP ADVANCED PLUS (Internal Hex)	3.0, 3.25	NP (3.25)
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)
	6.0	WP (6.0)
PALTOP DYNAMIC (Internal Hex)	3.0, 3.25	NP (3.25)
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)
	6.0	WP (6.0)
PALTOP DYNAMIC CONICAL (Internal Conical)	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)

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.

510(k) Summary
K222269
Terrats Medical SL
DESS® Dental Smart Solutions

October 25, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda, 75-99 08210 Barberà del Vallès Barcelona, Spain
Telephone	+34 935 646 006
Official Contact	Roger Terrats, CEO
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@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
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K212628, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K212577, DESS Dental Smart Solutions, Terrats Medical SL
K191986, DESS Dental Smart Solutions, Terrats Medical SL
K173908, DESS Dental Smart Solutions, Terrats Medical SL
K201334, Keystone Dental XL Dental Implant System, Keystone Dental, Inc.

K051614, PrimaConnex™ Internal Connection Implant System, Lifecore Biomedical, Inc.
K072768, Restore®, Stage-1®, Renova®, PrimaSolo®, and PrimaConnex® Dental Implants, Lifecore Biomedical, Inc.
K101545, Genesis Implant System, Keystone Dental, Inc.
K112795, Paltop Dental Implant System, Paltop Advanced Dental Solutions Ltd.
K210117, Paltop Narrow Implant, Paltop Advanced Dental Solutions, Ltd.
K220200, Paltop Conical Implant System, Paltop Advanced Dental Solutions, Ltd.

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 DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems

Compatible Implant System (Connection)	**Implant Body Diameter, mm**	**Implant Platform**
PRIMA CONNEX (Internal TiLobe, Tapered & Straight)	3.3, 3.5	3.5
	4.0, 4.1	4.1
	5.0	5.0
GENESIS (Internal TiLobe)	3.5, 3.8	3.5/3.8
	4.5	4.5
	5.5, 6.5	5.5/6.5
MOLARIS TILOBEMAXX (Internal TiLobe)	7	5.7
	8	6.5
	9	7.5
MOLARIS I-HEXMRT (Internal Hex)	7	5.7
	8	6.5
	9	7.5
PALTOP ADVANCED CLASSIC (Internal Hex)	3.25	NP (3.25)
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)
PALTOP ADVANCED PLUS (Internal Hex)	3.0, 3.25	NP (3.25)
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)
	6.0	WP (6.0)
PALTOP DYNAMIC (Internal Hex)	3.0, 3.25	NP (3.25)
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)
	6.0	WP (6.0)
PALTOP DYNAMIC CONICAL (Internal Conical)	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components to the DESS Dental Smart Solutions system, which includes abutments cleared previously in K170588, K173908, K191986, K203464, K212577, and K212628. This submission adds various abutments to eight (8) OEM implant lines from Keystone Dental, Inc., having three (3) implant-abutment connections (Internal TiLobe, Internal Hex, and Internal Conical). The subject device abutment

designs include Multi Unit Abutments (straight and angled 17° and 30°), Ti Base abutments, AURUM abutments, and Premilled Blank Abutments. Abutments are provided with the appropriate abutment screw (if applicable) for attachment to the corresponding implant, and the appropriate prosthetic screw (if applicable) for attachment of a screw-retained prosthesis. All abutments and screws are provided non-sterile.

A summary of the subject device abutment designs and the compatible OEM implants is provided in the table *Summary of Subject Device Abutment Designs and Compatible Implants* on the following page.

Summary of Subject Device Abutment Designs and Compatible Implants

Connection	Compatible Implant Systems			Subject Device Abutments				
		Implant Body Ø, mm	Implant Platform Ø, mm	Multi Unit Straight and 17° Angled	Multi Unit 30° Angled	Ti Bases	AURUM Bases	Premilled Blanks
Internal TiLobe	PRIMA CONNEX (Internal TiLobe, Tapered & Straight) K051614 K072768	3.3, 3.5	3.5	X	X	X	X	X
		4.0, 4.1	4.1	X	X	X	X	X
		5.0	5.0	X	X	X	X	X
	GENESIS (Internal TiLobe) K101545	3.5, 3.8	3.5/3.8	X	X	X	X	X
		4.5	4.5	X	X	X	X	X
		5.5, 6.5	5.5/6.5	X	X	X	X	X
	MOLARIS TILOBEMAXX (Internal TiLobe) K201334	7	5.7	X		X		X
		8	6.5	X		X		X
		9	7.5	X		X		X
Internal Hex	MOLARIS I-HEXMRT (Internal Hex) K201334	7	5.7	X		X		X
		8	6.5	X		X		X
		9	7.5	X		X		X
	PALTOP ADVANCED CLASSIC (Internal Hex) K112795	3.25	NP (3.25)	X		X	X	X
		3.75, 4.2, 5.0	SP (3.75/4.2/5.0)	X	X	X	X	X
	PALTOP ADVANCED PLUS (Internal Hex) K210117	3.0, 3.25	NP (3.25)	X		X	X	X
		3.75, 4.2, 5.0	SP (3.75/4.2/5.0)	X	X	X	X	X
		6.0	WP (6.0)	X		X	X	X
	PALTOP DYNAMIC (Internal Hex) K112795	3.0, 3.25	NP (3.25)	X		X	X	X
		3.75, 4.2, 5.0	SP (3.75/4.2/5.0)	X	X	X	X	X
		6.0	WP (6.0)	X		X	X	X
Internal Conical	PALTOP DYNAMIC CONICAL (Internal Conical) K220200	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)	X	X	X	X	X

The design dimensions and tolerances of subject device abutments and screws have been established on the basis of a contractual agreement and working relationship between Keystone Dental, Inc., and Terrats Medical SL to ensure that the abutments are designed to fit the corresponding Keystone Dental implants listed above.

Multi Unit Abutments

The Multi Unit Abutment is designed for attachment of multi-unit screw-retained restorations and is provided in three (3) designs, straight, angled 17°, and angled 30°. The straight Multi Unit Abutment is provided only in a non-engaging, threaded design that attaches directly to the implant, with a prosthetic platform diameter of 4.8 mm or 6.0 mm, and with a gingival height ranging from 1 mm to 5 mm. Straight Multi Unit Abutments are provided for all eight (8) compatible OEM implant lines. The angled Multi Unit Abutments are provided only in an engaging design that requires an abutment screw, with a prosthetic platform diameter of 4.8 mm or 6.0 mm, and with a gingival height ranging from 2.5 mm to 5 mm. The Multi Unit Abutments angled 30° are provided with a prosthetic platform diameter of 4.8 mm, and with a gingival height ranging from 3 mm to 5 mm. The Multi Unit Abutments angled 17° are provided for all eight (8) compatible OEM implant lines, and the Multi Unit Abutments angled 30° are provided for six (6) compatible OEM implant lines.

Ti Base and AURUM Base Abutments

Ti Base and AURUM Base abutments are designed for patient-specific abutment fabrication of a CAD-CAM zirconia superstructure on which a crown may be placed. They also may be used for support of a crown placed directly on the abutment. The cement recommended for bonding of superstructures is Multi-Link cement by Ivoclar Vivadent (K130436). All patient-specific abutment fabrication for Ti Base and AURUM Base abutments is by prescription on the order of the clinician. All zirconia superstructures for use with the subject device Ti Base and AURUM Base abutments will be made at a Terrats Medical validated milling center under FDA quality system regulations, and the material will conform to ISO 13356.

The Ti Bases and AURUM Bases are used as part of a two piece abutment, where the base is premanufactured from titanium alloy (Ti-6Al-4V ELI) and the top half is a CAD-CAM zirconia superstructure, milled at a validated milling center. These pieces are cemented together to form the final abutment.

Ti Base abutments are provided in engaging design and non-engaging designs for all eight (8) compatible OEM implant lines. Ti Base abutments are provided with a prosthetic platform diameter ranging from 4.1 mm to 7.0 mm, and a gingival height ranging from 1 mm to 3 mm. The prosthetic post height is 4.2 mm for all Ti Base abutments. Ti Base Abutments are manufactured from titanium alloy with a sandblasted surface treatment process (SelectGrip®) to aid in bonding retention of a cemented prosthesis. When used for a direct crown, Ti Base Interface may be used with a POM burn out sleeve, an exempt laboratory component not a subject of this submission, that is available for laboratory fabrication of the prosthesis.

The design parameters for the CAD-CAM zirconia superstructure, or traditional laboratory fabrication such as precious or non-precious cast, to be used on Ti Base Abutments are:

Minimum wall thickness – 0.4 mm
Minimum post height for single-unit restoration – 4.2 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures and PFM crowns for use with the titanium bases are for straight restorations only.

AURUM Base Abutments are provided in engaging design and non-engaging designs for six (6) compatible OEM implant lines. The design of the AURUM Base allows for easier instrument access to the abutment screw (up to 25° of instrument angulation) and allows for placement of the screw channel out of the esthetic region of the restoration. AURUM Base abutments are provided with a prosthetic platform diameter ranging from 4.1 mm to 6.0 mm, and a gingival height of 1 mm. Before attachment of the zirconia superstructure or crown, the AURUM

Base prosthetic post height is 3.0 mm. When used for a single-unit restoration the AURUM Base is to be used with a superstructure to create a minimum post height of 4.0 mm.

AURUM Base Abutments are manufactured from titanium alloy (Ti-6Al-4V) and 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.

The design parameters for the CAD-CAM zirconia superstructure, or traditional laboratory fabrication such as precious or non-precious cast, to be used on AURUM Base Abutments are:

Minimum wall thickness – 0.4 mm
Minimum post height for single-unit restoration – 4.0 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures and PFM crowns for use with the AURUM bases are for straight restorations only.

Premilled Blank Abutments

Premilled Blank Abutments are available in engaging designs only, for all eight (8) compatible OEM implant lines. All patient-specific abutment fabrication of Premilled Blank Abutments is by prescription on the order of the clinician, and will be done at a Terrats Medical validated milling center under FDA quality system regulations. The Premilled Blank Abutments have a maximum (before milling) diameter of 10 mm or 14 mm.

The design parameters for the CAD-CAM fabrication of patient-specific abutments from Premilled Blank Abutments are:

Minimum wall thickness – 0.45 mm
Minimum post height for single-unit restoration – 4.0 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
Pre-Milled Blanks are for straight abutments only

Screws

This submission includes ten (10) abutment screws to be used with the subject device abutments, and seven (7) prosthetic screws to be used with the subject device Multi Unit abutments. The screws have hex, hexalobular, or square drive instrument interfaces and are manufactured from titanium alloy (Ti-6Al-4V) with the Diamond-like Carbon (DLC) coating.

MATERIAL COMPOSITION

All subject device abutments, abutment screws, and prosthetic screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136. Abutment screws and prosthetic screws manufactured from ASTM F136 titanium alloy and coated with Diamond-like carbon (DLC) are provided to attach the abutments to the implant and to attach the attach the restoration to the abutment. The titanium alloy and DLC coating are identical to the material and coating used to manufacture DESS Dental Smart Solutions screws cleared in K212628, K212577, and K173908.

Ti Base Abutments have a sandblasted surface finish (SelectGrip®). This surface is identical to the surface used on DESS Dental Smart Solutions components cleared in K212628. The anodization process used for the subject AURUM Abutments is identical to the anodization treatment used to manufacture DESS Aurum Abutments cleared in K212628 and K173908.

All superstructures for use with the CAD-CAM abutments (Ti Bases and AURUM Bases) will be manufactured from zirconia conforming to ISO 13356. This material is identical to the zirconia material to be used to manufacture superstructures for DESS Dental Smart Solutions components cleared in K212628 and K173908.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence included:

sterilization validation according to ISO 17665-1 and ISO 17665-2, referenced from K212628;

biocompatibility according to ISO 10993-5 and ISO 10993-12, referenced from K212628;

non-clinical analysis performed to evaluate the metallic subject devices in the MR environment using scientific rationale and published literature (TO Woods, JG Delfino, and S Rajan, *"Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices," Journal of Testing and Evaluation*, Volume 49, No. 2, 2021, pp. 783-795); the analysis addressed parameters per the FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (issued May 2021) including magnetically induced displacement force and torque; and

static compression and compression fatigue testing of worst-case constructs comprising the subject device Multi Unit Angled Abutments and compatible OEM implants in conformance with ISO 14801.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device abutments are substantially equivalent in intended use to the primary predicate device cleared in K212628 and the additional predicate devices cleared in 212577 and K173908. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. The Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of K212628, K212577, and K173908, except for the list of compatible OEM implants.

Differences between the subject device IFUS and that of the additional predicate K201334 include additional language in K201334 describing the use of the dental implants that is not applicable to the subject device abutments. The IFUS for K201334 does include language regarding support of dental prostheses that is similar to that of the subject device.

All subject device abutments are similar or identical in design, materials and technological characteristics to corresponding abutments of the primary predicate device K212628 and the additional predicate devices K212577, and K173908. In some cases, the names of the abutments vary slightly from the subject device to the previous submissions (K212628, K212577, and K173908).

The SelectGrip® surface on the subject device Ti Base Abutments is identical to the Select Grip® surface on equivalent abutments cleared in K212628 and K173908. The gold anodized surface on the subject device AURUM Base Abutments is identical to the anodized surface on Aurum Abutments of the predicate devices K212628 and K173908.

The cement recommended in labeling for bonding of superstructures is Multi-Link cement from Ivoclar Vivadent, cleared under K130436. This is the same cement recommended in labeling for the primary predicate device K212628 and the additional predicate device K173908.
All screws are identical in design, materials and technological characteristics to those cleared in predicate devices K212628, K212577, and K173908, except for threads and lengths that accommodate the new compatibilities. The

Diamond-like carbon (DLC) coating applied to all screws is identical to the DLC coating on screws cleared in K212628, K212577, and K173908.

The range of dimensions of the subject device abutments are encompassed by the corresponding predicate devices, including the abutment-implant platform diameter, prosthetic platform diameter, gingival height, and abutment angulation. The additional predicate device K212577 includes Premilled Blank abutments designs with up to 30° of angulation, which is the maximum angulation of the subject Multi Unit Abutments. The additional predicate device K201334, in addition to the implant compatibilities, is for substantial equivalence of the implant-abutment platform diameter (up to 7.5 mm) and abutment prosthetic platform diameter (up to 7 mm).

All subject device components are provided non-sterile and are to be sterilized by the same moist heat cycle recommended in the predicate submissions K212628, K212577, and K173908. The subject devices are packaged in either a PETG blister pack or a PET bag, the same packaging as cleared in K212628, K212577, and K173908.

The risks associated with use of the subject device Angled Multi Unit Abutments in combination with the compatible implants are mitigated by the mechanical testing provided in Section 18 *Performance Testing – Bench.*

CONCLUSION

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

Table of Substantial Equivalence – Indications for Use Statement

<table>
<tr><th></th><th>Indications for Use Statement</th></tr>
<tr><td>Subject Device

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 DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems
<table>
<tr><th>Compatible Implant System
(Connection)</th><th>Implant Body Diameter, mm</th><th>Implant Platform</th></tr>
<tr><td rowspan="3">PRIMA CONNEX
(Internal TiLobe, Tapered & Straight)</td><td>3.3, 3.5</td><td>3.5</td></tr>
<tr><td>4.0, 4.1</td><td>4.1</td></tr>
<tr><td>5.0</td><td>5.0</td></tr>
<tr><td rowspan="3">GENESIS
(Internal TiLobe)</td><td>3.5, 3.8</td><td>3.5/3.8</td></tr>
<tr><td>4.5</td><td>4.5</td></tr>
<tr><td>5.5, 6.5</td><td>5.5/6.5</td></tr>
<tr><td rowspan="3">MOLARIS TILOBEMAXX
(Internal TiLobe)</td><td>7</td><td>5.7</td></tr>
<tr><td>8</td><td>6.5</td></tr>
<tr><td>9</td><td>7.5</td></tr>
<tr><td rowspan="3">MOLARIS I-HEXMRT
(Internal Hex)</td><td>7</td><td>5.7</td></tr>
<tr><td>8</td><td>6.5</td></tr>
<tr><td>9</td><td>7.5</td></tr>
<tr><td rowspan="2">PALTOP ADVANCED CLASSIC
(Internal Hex)</td><td>3.25</td><td>NP (3.25)</td></tr>
<tr><td>3.75, 4.2, 5.0</td><td>SP (3.75/4.2/5.0)</td></tr>
<tr><td rowspan="3">PALTOP ADVANCED PLUS
(Internal Hex)</td><td>3.0, 3.25</td><td>NP (3.25)</td></tr>
<tr><td>3.75, 4.2, 5.0</td><td>SP (3.75/4.2/5.0)</td></tr>
<tr><td>6.0</td><td>WP (6.0)</td></tr>
<tr><td rowspan="3">PALTOP DYNAMIC
(Internal Hex)</td><td>3.0, 3.25</td><td>NP (3.25)</td></tr>
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<tr><td>PALTOP DYNAMIC CONICAL
(Internal Conical)</td><td>3.25, 3.75, 4.2, 5.0</td><td>CC (3.25/3.75/4.2/5.0)</td></tr>
</table></td></tr>
</table>

Primary Predicate Device

K212628

DESS Dental Smart Solutions

Terrats Medical SL

DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed custom abutments for use with DESS Bases or Blanks 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 Name
Astra Tech EV	3.0	3.0
	3.6	3.6
	4.2	4.2
	4.8	4.8
	5.4	5.4
Astra Tech OsseoSpeed™	3.0	3.0
	3.5/4.0	3.5/4.0
	4.5/5.0	4.5/5.0
BioHorizons	3.0, 3.4, 3.8	3.0
	3.8, 4.6	3.5
	4.6, 5.8	4.5
	5.8	5.7
Biomet 3i Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
Biomet 3i OSSEOTITE®	3.25	3.4
	3.75, 4.0	4.1
	5.0	5.0
Camlog	3.8	3.8
	4.3	4.3
	5.0	5.0
FRIADENT XiVE®	3.8	3.8
	4.5	4.5
	5.5	5.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive®, NobelParallel Conical	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
NobelReplace® Trilobe	4.3	RP
	5.0	WP
	6.0	6.0
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
Osstem TS	3.5	Mini
	4.0, 4.5, 5.0, 6.0, 7.0	Regular
Straumann BLX	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann® Bone Level	3.3	NC
	4.1/4.8	RC
Straumann® Tissue Level	3.3	NNC
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

Reference Device

K212577

DESS Dental Smart Solutions

Terrats Medical SL

DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed custom abutments for use with Pre-milled Blank 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
NobelActive®, NobelParallel Conical	3.5	NP
	4.3, 5.0	RP
	5.5	WP
Straumann® Bone Level	3.3	NC
	4.1/4.8	RC
Zimmer Screw-Vent® / Tapered Screw-Vent®	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

Reference Device

K173908

DESS Dental Smart Solutions

Terrats Medical SL

DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed custom abutments for use with Aurum™ Abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems

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
FRIADENT XiVE	3.4, 3.8, 4.5	3.4, 3.8, 4.5
NobelActive®	3.5, 4.3, 5.0	NP, RP
NobelReplace® Conical	3.5, 4.3, 5.0	NP, RP
NobelReplace® Trilobe	3.5, 4.3, 5.0	NP, RP, WP
Brånemark	3.5, 3.75/4.0, 5.0	NP, RP, WP
Straumann® Bone Level	3.3, 4.1, 4.8	NC, RC
Straumann® Tissue Level	3.3, 4.1, 4.8	RN, WN
Tapered Screw-Vent®	3.7, 4.1, 4.7, 6.0	3.5, 4.5, 5.7

Reference Device

K201334

Keystone Dental XL Dental Implant System

Keystone Dental, Inc.

The XL Dental Implant System is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This XL implant system provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Table of Substantial Equivalence – Technological Characteristics, Multi Unit Abutments

	Subject Device			Primary Predicate Device	Reference Device	Reference Device
	K222269 DESS Dental Smart Solutions Terrats Medical SL			**K212628 DESS Dental Smart Solutions Terrats Medical SL**	**K191986 DESS Dental Smart Solutions Terrats Medical SL**	**K201334 Keystone Dental XL Dental Implant System Keystone Dental, Inc.**
Reason for Predicate Device	Not applicable			Designs; materials; manufacturing; sterilization	Designs for Multi Unit Abutments	Designs
Product Codes	NHA			NHA	NHA	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla			Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Abutment Designs						
Abutment Types	Multi Unit, Straight (0°)	Multi Unit, 17°	Multi Unit, 30°	Multi Unit	Multi Unit	Healing Abutments; Titanium Cylinder (temporary restorations); Titanium Abutments (permanent restorations)
Prosthesis Attachment	Screw Retained	Screw Retained	Screw Retained	Screw Retained	Screw Retained	Cement-retained Screw Retained
Restoration	Multi-unit	Multi-unit	Multi-unit	Multi-unit	Multi-unit	Single-unit Multi-unit
Prosthetic Interface Connections	Internal	Internal	Internal	Internal	Internal	Internal External
Abutment/Implant Platform Diameter, mm	3.25 – 7.5	3.25 – 7.5	3.25 – 6.5	3.0 – 7.0	3.3 – 4.8	5.7 – 7.5
Prosthetic Platform Diameter, mm	4.8 – 6.0	4.8 – 6.0	4.8	4.8	4.8	7.0 – 9.0
Gingival Height, mm	1.0 – 5.0	2.5 – 5.0	3.0 – 5.0	1.5 – 3.5	2.5 – 4.5	1 – 6
Abutment Angulation, degrees	Straight (0°)	17°	30°	Straight (0°)	17°, 30°	Straight (0°)
Abutment Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Titanium alloy, ASTM F136
Superstructure Material	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Screw Material	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI DLC coating	Titanium alloy, ASTM F136
How Provided						
Abutments	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Sterile by irradiation
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use

Table of Substantial Equivalence – Technological Characteristics, Ti Base and AURUM Base Abutments

	Subject Device		**Primary Predicate Device**	**Reference Device**	**Reference Device**
	K222269 **DESS Dental Smart Solutions** **Terrats Medical SL**		**K212628** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K173908** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K201334** **Keystone Dental XL Dental Implant System** **Keystone Dental, Inc.**
Reason for Predicate Device	Not applicable		Designs; materials; manufacturing; sterilization	Designs; materials; manufacturing; sterilization	Designs
Product Codes	NHA		NHA	NHA	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla		Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Abutment Designs					
Abutment Types	Ti Base	AURUM Base	Ti Base Interface, DESS Aurum Base, ELLIPTIBase,	AURUM Base	Healing Abutments; Titanium Cylinder (temporary restorations); Titanium Abutments (permanent restorations)
Prosthesis Attachment	Cement-retained Screw Retained	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	Single-unit Multi-unit
Prosthetic Interface Connections	Internal	Internal	Internal	Internal External	Internal External
Abutment/Implant Platform Diameter, mm	3.25 – 7.5	3.25 – 6.5	3.0 – 5.7	3.3 – 6.5	5.7 – 7.5
Prosthetic Platform Diameter, mm	4.1 – 7.0	4.1 – 6.0	3.4 – 5.5	4.5 – 6.8	7.0 – 9.0
Gingival Height, mm	1.0 – 3.0	1.0	1.0 – 3.5	Not stated	1 – 6
Abutment Angulation, degrees	Straight (0°)	Straight (0°)	Straight (0°)	Straight (0°)	Straight (0°)
Abutment Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Titanium alloy, ASTM F136
Superstructure Material	Zirconia, ISO 13356	Zirconia, ISO 13356	Zirconia, ISO 13356	Not applicable	Not applicable
Superstructure design parameters					
Minimum wall thickness, mm	0.4	0.4	0.4	0.4	Not applicable
Minimum post height for single-unit restoration, mm	4.2	4.0	4.0	4.0	Not applicable
Minimum gingival height, mm	0.5	0.5	0.5	Not stated	Not applicable
Maximum gingival height, mm	6.0	6.0	6.0	6.0	Not applicable
Angulation	Straight only, no angulation	Straight only, no angulation	Straight only, no angulation	Straight only, no angulation	Not applicable
Screw Material	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI DLC coating	Titanium alloy, ASTM F136
How Provided					
Abutments	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Sterile by irradiation
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use

Table of Substantial Equivalence – Technological Characteristics, Premilled Blank Abutments

	Subject Device	**Primary Predicate Device**	**Reference Device**	**Reference Device**
	K222269 **DESS Dental Smart Solutions** **Terrats Medical SL**	**K212628** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K212577** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K201334** **Keystone Dental XL Dental Implant System** **Keystone Dental, Inc.**
Product Codes	NHA	NHA	NHA	DZE, NHA
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Abutment Designs				
Abutment Types	Premilled Blank	Pre-milled Blank	Premilled Blank	Healing Abutments; Titanium Cylinder (temporary restorations); Titanium Abutments (permanent restorations)
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
Prosthetic Interface Connections	Internal	Internal External	Internal	Internal External
Abutment/Implant Platform Diameter, mm	3.25 – 7.5	3.0 – 7.0	3.3 – 5.7	5.7 – 7.5
Prosthetic Platform Diameter, mm	Not applicable (defined by interproximal space)	Not applicable	Not applicable	7.0 – 9.0
Gingival Height, mm	6.0 (maximum)	6.0 (maximum)	6.0 (maximum)	1 – 6
Abutment Angulation, degrees	Straight (0°)°	Straight (0°)	Up to 30°	Straight (0°)
Abutment Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI Co-Cr-Mo Alloy	Ti-6Al-4V ELI Co-Cr-Mo Alloy	Titanium alloy, ASTM F136
Final abutment design parameters				
Minimum wall thickness, mm	0.45	0.45	0.45	Not applicable
Minimum post height for single-unit restoration, mm	4.0	4.0	4.0	Not applicable
Minimum gingival height, mm	0.5	0.5	0.3	Not applicable
Maximum gingival height, mm	6.0	6.0	6.0	Not applicable
Angulation	Straight only, no angulation	Straight only, no angulation	Straight only, no angulation	Not applicable
Screw Material	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI DLC coating	Ti-6Al-4V ELI ± DLC coating *(Compatible screws were cleared in prior 510(k) submissions)*	Titanium alloy, ASTM F136
How Provided				
Abutments	Non-sterile	Non-sterile	Non-sterile	Sterile by irradiation
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use