April 24, 2024

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

Re: K240208
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: January 24, 2024
Received: January 25, 2024

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

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

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

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K240208

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 Ti Base abutments or Pre-Milled Blank abutments 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, mm
Astra Tech EV (Internal Taper)	3.0	3.0
	3.6	3.6
	4.2	4.2
	4.8	4.8
Astra Tech OsseoSpeed TX (Internal Taper)	3.0	3.0
	3.5, 4.0	3.5/4.0
	4.5, 5.0	4.5/5.0
BioHorizons Internal (Internal Hex)	3.0, 3.4, 3.8	3.0
	3.8, 4.2, 4.6	3.5
	4.6, 5.2, 5.8	4.5
	5.8, 7.0, 8.0	5.7
Biomet 3i OSSEOTITE® (External Hex)	3.25	3.4
	3.75, 4.0	4.1
	5.0	5.0
Dentium Superline (Internal Taper)	3.6, 4.0, 4.5, 5.0, 6.0, 7.0	3.3
DESS Active (Internal Conical)	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
	5.5	WP
DESS Bone Level (Internal Conical)	3.3	NC
	4.1, 4.8	RC
PrimaConnex Prima Plus (Internal TiLobe)	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)

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
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 PAI Paltop PAI TC (Internal Hex)	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 Paltop Conical Active (PCA) (Internal Conical)	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)
MIS Seven MIS M4 (Internal Hex)	3.3	NP (3.1)
	3.75, 4.2	SP (3.5)
	5.0, 6.0	WP (4.5)
Neodent (Morse taper GM)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
NobelActive® NobelReplace Conical NobelParallel Conical (Conical Connection)	3.0	3.0
	3.5, 3.75	NP (3.5)
	4.3, 5.0	RP (3.9)
	5.5	WP (5.1)
NobelReplace (Internal Tri-channel)	3.5	NP (3.5)
	4.3	RP (4.3)
Osstem® TS Hiossen® ET (Internal Taper)	3.5	Mini
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC
	4.1, 4.8	RC
Zimmer Screw-Vent® Tapered Screw-Vent® (Internal Hex)	3.3, 3.7, 4.1	3.5
	4.7	4.5
TSX™ Implant System (Internal Hex)	3.7, 4.1, 4.7	3.5

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
K240208
Terrats Medical SL
DESS Dental Smart Solutions

April 24, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda, 75-99 Barberà del Vallès 08210 Barcelona, Spain
Telephone	+34 935 646 006
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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 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 AND REFERENCE DEVICE INFORMATION

K233316, DESS Dental Smart Solutions, Terrats Medical SL
K231434, DESS Dental Smart Solutions, Terrats Medical SL
K222288, DESS Dental Smart Solutions, Terrats Medical SL
K222269, DESS Dental Smart Solutions, Terrats Medical SL
K212628, DESS Dental Smart Solutions, Terrats Medical SL
K191986, DESS Dental Smart Solutions, Terrats Medical SL
K170588, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices for OEM implant body clearances

K120414, OsseoSpeed™ Plus, Astra Tech AB
K111287, Astra Tech Implant System Plus, Astra Tech AB
K101732, Astra Tech Implant System, Astra Tech AB
K042429, BioHorizons The Prodigy System™ Endosseous Implants, BioHorizons Implant Systems, Inc.
K071638, BioHorizons Tapered Internal Implant System, BioHorizons Implant Systems, Inc.
K093321, BioHorizons Laser-Lok 3.0 Implant System, BioHorizons Implant Systems, Inc.
K063341, 3i OSSEOTITE® Certain® Dental Implants, Implant Innovations, Inc.
K160965, SuperLine, Dentium Co., Ltd.
K212538, DESS Dental Implants, Terrats Medical SL
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.
K201334, Keystone Dental XL Dental Implant System, Keystone Dental Inc.
K112795, Paltop Dental Implant System, Paltop Advanced Dental Solutions Ltd.
K210117, Paltop Narrow Implant, Paltop Advanced Dental Solutions, Ltd
K130462, Paltop Narrow Implant, Paltop Advanced Dental Solutions Limited
K220200, Paltop Conical Implant System, Paltop Advanced Dental Solutions, Ltd
K180282, MIS Internal Hex Dental Implant System, MIS Implants Technologies Ltd.
K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários SA
K180536, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
K201225, Neodent Implant System – GM Helix Implants 7.0, JJGC Indústria e Comércio de Materiais Dentários S.A.
K142260, NobelActive®, Nobel Biocare AB
K073142, NobelReplace Hexagonal Implants, Nobel Biocare AB
K173418, NobelParallel™ Conical Connection, Nobel Biocare AB
K050705, TiUnite Implants®, Nobel Biocare AB
K050406, NOBELSPEEDY™ Implants, Nobel Biocare USA LLC
K050258, Groovy Implants, Nobel Biocare AB
K023113, Replace TiUnite Endosseous Implant, Nobel Biocare USA, Inc.
K161604, OSSTEM Implant System, Osstem Implant Co., Ltd
K173961, Straumann® BLX Implant System, Institut Straumann AG
K181703, Straumann® BLX Line Extension – Implants, SRAs and Anatomic Abutments, Institut Straumann AG
K191256, Straumann BLX Ø3.5 mm Implants, Institut Straumann AG
K210855, Straumann BLX Implant System, Institut Straumann AG
K212533, BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants, Institut Straumann AG
K140878, Straumann® Bone Level Tapered Implants, Straumann USA, LLC
K013227, Screw Vent Implant; Tapered Screw Vent Implant, Sulzer Dental, Inc.
K072589, Tapered Screw-Vent Implant, 4.1mmD, Zimmer Dental, Inc.
K220978, TSX™ Implants, Biomet 3i LLC

The primary predicate device is K233316.
The reference devices K231434, K222288, K222269, K212628, K191986, and K170588 include documentation of the compatibility of the subject device abutments with the corresponding OEM implant bodies.

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 Ti Base abutments or Pre-Milled Blank abutments 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, mm
Astra Tech EV (Internal Taper)	3.0	3.0
	3.6	3.6
	4.2	4.2
	4.8	4.8
Astra Tech OsseoSpeed TX (Internal Taper)	3.0	3.0
	3.5, 4.0	3.5/4.0
	4.5, 5.0	4.5/5.0
BioHorizons Internal (Internal Hex)	3.0, 3.4, 3.8	3.0
	3.8, 4.2, 4.6	3.5
	4.6, 5.2, 5.8	4.5
	5.8, 7.0, 8.0	5.7
Biomet 3i OSSEOTITE® (External Hex)	3.25	3.4
	3.75, 4.0	4.1
	5.0	5.0
Dentium Superline (Internal Taper)	3.6, 4.0, 4.5, 5.0, 6.0, 7.0	3.3
DESS Active (Internal Conical)	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
	5.5	WP
DESS Bone Level (Internal Conical)	3.3	NC
	4.1, 4.8	RC
PrimaConnex Prima Plus (Internal TiLobe)	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 PAI Paltop PAI TC (Internal Hex)	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 Paltop Conical Active (PCA) (Internal Conical)	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)
MIS Seven MIS M4 (Internal Hex)	3.3	NP (3.1)
	3.75, 4.2	SP (3.5)
	5.0, 6.0	WP (4.5)

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
Neodent (Morse taper GM)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
NobelActive® NobelReplace Conical NobelParallel Conical (Conical Connection)	3.0	3.0
	3.5, 3.75	NP (3.5)
	4.3, 5.0	RP (3.9)
	5.5	WP (5.1)
NobelReplace (Internal Tri-channel)	3.5	NP (3.5)
	4.3	RP (4.3)
Osstem® TS Hiossen® ET (Internal Taper)	3.5	Mini
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC
	4.1, 4.8	RC
Zimmer Screw-Vent® Tapered Screw-Vent® (Internal Hex)	3.3, 3.7, 4.1	3.5
	4.7	4.5
TSX™ Implant System (Internal Hex)	3.7, 4.1, 4.7	3.5

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components to the DESS Dental Smart Solutions system, which includes dental implants, abutments, and prosthetic components cleared previously in various submissions. The previously cleared abutments and prosthetic components are compatible with a variety of original equipment manufacturer (OEM) dental implants as well as DESS Dental Smart Solutions dental implants.

This submission adds various abutments to the DESS and OEM implant lines as summarized on the following pages in **Table 1** ***Summary of Subject Device Abutment Designs***, and **Table 2** ***Summary of Subject Device Abutment Sizes***.

The subject device abutment designs include Cover Screws, Healing Abutments, Temporary Abutments, Ti Base Abutments, AURUM Base Abutments (Ti Base abutments with a screw channel design that allows easier instrument access to the abutment screw), CoCr Base Abutments, Pre-Milled Blank Abutments, Multi-Unit Abutments (straight and angled), DESSLoc Abutments (Locator-type abutments), and abutment screws.

Table 1 – Summary of Subject Device Abutment Designs

Compatible Implant Systems	DESS Abutment System	Cover Screws	Healing Abutment	Temporary Abutment	Ti Base Engaging and Non-engaging	AURUM Base Engaging and Non-engaging	CoCr Base Engaging and Non-engaging	Pre-Milled Blank Engaging	Multi-Unit Abutment Straight	Multi-Unit Abutment Angled	DESSLoc Abutment	Screws
Astra Tech EV	Conic EVO				X			X				X
Astra Tech OsseoSpeed TX	Internal Hex Conic		X	X	X							X
BioHorizons Internal	Internal Hex BH		X					X				
Biomet 3i OSSEOTITE®	External Hex USA				X							
Dentium SuperLine	Conic DENT					X						
DESS Active	DESS Active	X										
DESS Bone Level	DESS Bone Level	X										
Keystone (Internal TiLobe) PrimaConnex Prima Plus Genesis Molaris Tilobemaxx	Internal TiLobe				X			X				
Keystone (Internal Hex) Molaris I-Hexmrt Paltop Advanced Classic Paltop Advanced Plus Paltop Dynamic Paltop PAI Paltop PAI TC	Internal Hex				X			X				
Keystone (Internal Conical) Paltop Dynamic Conical Paltop Conical Active (PCA)	Internal Conical				X			X				
MIS Seven MIS M4	Internal Hex MI		X	X	X	X	X	X	X		X	X
Neodent Grand Morse	Neo GM				X			X	X			X
NobelActive® NobelReplace Conical NobelParallel Conical	Active Hex		X	X	X			X				
NobelReplace (Tri-channel)	Tri-lobe									X		X
Osstem® TS Hiossen® ET	Conic OSS							X				
Straumann BLX	Conical BLX				X			X				X
Straumann Bone Level	Conical BL			X	X		X	X				X
Zimmer Screw-Vent® Zimmer Tapered Screw-Vent®	Internal Hex USA				X			X				
TSX™ Implant System	Internal Hex USA				X							

Table 2 – Summary of Subject Device Abutment Sizes

OEM Compatible Implants			Subject Device Abutments										
Compatible Implant Lines	**Implant Body Ø**	**Implant Platform Ø**	**Cover Screws**	**Healing**	**Temporary**	**Ti Base**	**AURUM Base**	**CoCr Base**	**Pre-Milled Blank**	**Multi-Unit Straight**	**Multi-Unit Angled**	**DESSLoc**	**Screws**
Astra Tech EV	3.0	3.0				X			X				
	3.6	3.6							X				X
	4.2	4.2							X				X
	4.8	4.8											X
Astra Tech OsseoSpeed TX	3.0	3.0		X	X	X							
	3.5, 4.0	3.5/4.0											X
	4.5, 5.0	4.5/5.0											X
BioHorizons Internal	3.0, 3.4, 3.8	3.0		X					X				
	3.8, 4.2, 4.6	3.5							X				
	4.6, 5.2, 5.8	4.5							X				
	5.8, 7.0, 8.0	5.7							X				
Biomet 3i OSSEOTITE®	3.25	3.4				X							
	3.75, 4.0	4.1				X							
	5.0	5.0				X							
Dentium SuperLine	3.6, 4.0, 4.5, 5.0, 6.0, 7.0	3.3					X						
DESS Active	3.0	3.0	X										
	3.5	NP	X										
	4.3, 5.0	RP	X										
	5.5	WP	X										
DESS Bone Level	3.3	NC	X										
	4.1, 4.8	RC	X										
PrimaConnex Prima Plus	3.3, 3.5	3.5				X			X				
	4.0, 4.1	4.1				X			X				
	5.0	5.0				X			X				
Genesis	3.5, 3.8	3.5/3.8				X			X				
	4.5	4.5				X			X				
	5.5, 6.5	5.5/6.5				X			X				
Molaris Tilobemaxx	7	5.7				X			X				
	8	6.5				X			X				
	9	7.5				X			X				
Molaris I-Hexmrt	7	5.7				X			X				
	8	6.5				X			X				
	9	7.5				X			X				
Paltop Advanced Classic	3.25	NP (3.25)				X			X				
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)				X			X				

Table 2 – Summary of Subject Device Abutment Sizes

OEM Compatible Implants			Subject Device Abutments										
Compatible Implant Lines	**Implant Body Ø**	**Implant Platform Ø**	**Cover Screws**	**Healing**	**Temporary**	**Ti Base**	**AURUM Base**	**CoCr Base**	**Pre-Milled Blank**	**Multi-Unit Straight**	**Multi-Unit Angled**	**DESSLoc**	**Screws**
Paltop Advanced Plus	3.0, 3.25	NP (3.25)				X			X				
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)				X			X				
	6.0	WP (6.0)				X			X				
Paltop Dynamic	3.0, 3.25	NP (3.25)				X			X				
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)				X			X				
	6.0	WP (6.0)				X			X				
Paltop PAI Paltop PAI TC	3.25	NP (3.25)				X			X				
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)				X			X				
	6.0	WP (6.0)				X			X				
Paltop Dynamic Conical Paltop Conical Active PCA	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)				X			X				
MIS Seven MIS M4	3.3	NP (3.1)				X		X	X				X
	3.75, 4.2	SP (3.5)		X	X	X	X	X	X	X		X	X
	5.0, 6.0	WP (4.5)		X	X	X	X	X	X	X		X	X
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM				X			X	X			X
NobelActive® NobelReplace Conical Nobel Parallel Conical	3.0	3.0		X	X	X			X				
	3.5, 3.75	NP (3.5)				X			X				
	4.3, 5.0	RP (3.9)							X				
	5.5	WP (5.1)		X	X								
NobelReplace	3.5	NP (3.5)									X		X
	4.3	RP (4.3)									X		X
Osstem® TS Hiossen® ET	3.5	Mini							X				
	4.0, 4.5, 5.0, 55, 6.0, 7.0	Regular							X				
Straumann BLX	3.5, 3.75, 4.0, 4.5	RB				X			X				X
	5.0, 5.5, 6.5	WB				X			X				X
Straumann Bone Level	3.3	NC				X			X				X
	4.1, 4.8	RC							X				X
Zimmer Screw-Vent® Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5				X			X				
	4.7	4.5							X				
TSX™ Implant System	3.7, 4.1, 4.7	3.5				X							

SUBJECT DEVICE DESIGNS

Cover Screws are provided only for the DESS Active implants (platforms 3.0, NP, RP, and WP), and for the DESS Bone Level implants (platforms NC, RC). The coronal diameter of the Cover Screws ranges from 2.8 mm to 5.1 mm. Cover Screws are made of titanium alloy (Ti-6Al-4V).

Healing Abutments are provided for Astra Tech OsseoSpeed TX implants with a 3.0 platform, BioHorizons Internal implants with a 3.0 platform, MIS Seven and MIS M4 implants with SP (3.5) and WP (4.5) platforms, and Nobel Biocare conical connection implants with 3.0 and WP (5.1) platforms. The Healing Abutments are provided in gingival heights from 3 mm to 5 mm to aid in contouring the gingiva during healing. Healing abutments are made of titanium alloy (Ti-6Al-4V).

Temporary Abutments are provided for Astra Tech OsseoSpeed TX implants with a 3.0 platform, MIS Seven and MIS M4 implants with SP (3.5) and WP (4.5) platforms, and for Nobel Biocare conical connection implants with 3.0 and WP (5.1) platforms. Temporary Abutments are available for single-unit and multiple-unit restorations, the former with engaging connections to the implants and the latter with non-engaging connections. All Temporary Abutments have a gingival height of 1.5 mm and are made of titanium alloy (Ti-6Al-4V).

Ti Base Abutments are provided in engaging and non-engaging designs. The Ti Base Abutments are for custom abutment fabrication of a CAD-CAM zirconia superstructure on which a crown may be placed. They also may be used to support a crown placed directly on the abutment. The two-pieces of the Ti Base abutment which compose the final abutment consists of the pre-manufactured titanium base component composed of titanium alloy and the CAD-CAM patient matched superstructure composed of zirconia. The cement recommended for bonding of superstructures is Multi-Link cement by Ivoclar Vivadent. Ti Base Abutments are manufactured from titanium alloy (Ti 6Al 4V) with the SelectGrip® surface. When used for a direct crown, Ti Base Abutments 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 to be used on Ti Base Abutments are the same as cleared in K222288:

Minimum wall thickness – 0.4 mm
Minimum post height for single-unit restoration (length above the abutment collar/gingival height) – 4.2 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
Maximum angulation – refer to **Table 3** ***Ti Base Abutments***.

Table 3 – Ti Base Abutments

Compatible Implant System	Compatible Body Diameter, mm	Compatible Implant Platform Name	Gingival Height,* mm	Prosthetic Platform Diameter, mm	Maximum Angulation
Astra Tech EV	3.0	3.0	1.5	3.85	0°
Astra Tech OsseoSpeed™	3.0	3.0	1.5	3.85	0°
Biomet 3i OSSEOTITE®	3.25	3.4	0.3 – 3.0	4.5 – 5.2	30°
	3.75, 4.0	4.1			30°
	5.0	5.0			30°
Keystone/Paltop					
PrimaConnex Prima Plus	3.3, 3.5	3.5	1.0 or 2.0 **For 3 mm GH max angle = 0°**	4.1 – 7.0	30°
	4.0, 4.1	4.1			30°
	5.0	5.0			30°
Genesis	3.8, 3.5	3.5/3.8			30°
	4.5	4.5			30°
	5.5, 6.5	5.5/6.5			30°
Molaris Tilobemaxx	7	5.7			30°
	8	6.5			30°
	9	7.5			30°

Compatible Implant System	Compatible Body Diameter, mm	Compatible Implant Platform Name	Gingival Height,* mm	Prosthetic Platform Diameter, mm	Maximum Angulation
Molaris I-Hexmrt	7	5.7	1.0 or 2.0 **For 3 mm GH max angle = 0°**	6.0 – 7.0	30°
	8	6.5			30°
	9	7.5			30°
Paltop Advanced Classic	3.25	NP (3.25)	1.0 or 2.0 **For 3 mm GH max angle = 0°**	4.25 – 5.7	30°
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)			30°
Paltop Advanced Plus	3.0, 3.25	NP (3.25)			30°
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)			30°
	6.0	WP (6.0)			30°
Paltop Dynamic	3.0, 3.25	NP (3.25)			30°
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)			30°
	6.0	WP (6.0)			30°
Paltop PAI Paltop PAI TC	3.25	NP (3.25)			30°
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)			30°
	6.0	WP (6.0)			30°
Paltop Dynamic Conical Paltop Conical Active PCA	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)	1.0 – 2.0	4.3	30°
MIS Seven MIS M4	3.3	NP (3.1)	0.3 – 3.0	4.5 – 5.7	0°
	3.75, 4.2	SP (3.5)			0°
	5.0, 6.0	WP (4.5)			0°
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM	1.5	3.85	0°
NobelActive® NobelReplace Conical NobelParallel Conical	3.0	3.0	1.5	3.5 – 3.85	0°
	3.5, 3.75	NP (3.5)			0°
Straumann® BLX	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB/WB, WB	1.5	3.85	0°
Straumann® Bone Level	3.3	NC	0.5 – 1.5	3.85 – 4.95	0°
Zimmer Screw-Vent® Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5	1.5	3.85	0°
Zimmer TSX™	3.7, 4.1, 4.7	3.5	1.5	3.85	0°

***** *Gingival height in the Ti Base*

All patient-specific custom abutment fabrication for Ti Base Abutments and AURUM Base Abutments (described below) 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.

AURUM Base Abutments are provided in engaging and non-engaging designs for Dentium SuperLine implants with a 3.3 platform and for MIS Seven and MIS M4 implants with SP (3.5) and WP (4.5) platforms. The two-pieces of the AURUM Base abutment which compose the final abutment consists of the pre-manufactured titanium base component composed of titanium alloy and the CAD-CAM patient matched superstructure composed of zirconia. The design of the AURUM Base allows for easier instrument access to the abutment screw 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 4.5 mm to 5.7 mm, and a gingival height (in the base) of 0.3 mm or 0.9 mm. When used for a single-unit restoration the AURUM Base is to be used with a superstructure to create a minimum post height (length above the abutment collar/gingival height) of 4.0 mm. ARUM Base Abutments are to be used for straight abutments only, no angulation.

AURUM Base Abutments are manufactured from titanium alloy (Ti 6Al 4V) and anodized a gold color, and the SelectGrip® surface to aid in bonding retention. The design of the AURUM Base abutments, including the titanium

alloy, anodization treatment, and SelectGrip® surface is similar to that of DESS Aurum Abutments cleared in K222269. AURUM Base Abutments are not intended for angulation correction.

The design parameters for the CAD-CAM zirconia superstructure to be used on AURUM Base Abutments are the same as cleared in K222269:
Minimum wall thickness – 0.4 mm
Minimum post height for single-unit restoration (length above the abutment collar/gingival height) – 4.0 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures are for straight abutments only.

CoCr Base Abutments are provided for MIS Seven and MIS M4 implants with NP (3.1), SP (3.5), and WP (4.5) platforms, in engaging designs for single-unit restorations and non-engaging designs for multi-unit restorations. The two-pieces of the CoCr Base abutment which compose the final abutment consists of the pre-manufactured CoCr base component composed of CoCr alloy and the CAD-CAM patient matched superstructure composed of zirconia. CoCr Base Abutments also may be used as part of a welded multi-unit construct, intended to be used with the included exempt POM burnout sleeve for wax-up and casting of a crown or bridge from a non-precious metal alloy. CoCr Base Abutments have a gingival height of 1.5 mm, a prosthetic platform diameter of 4.5 mm to 4.9 mm, and are made from Co-Cr-Mo alloy. The design of the CoCr Base Abutments is similar to CoCr Base Abutments cleared in K222288. CoCr Base Abutments are not intended for angulation correction.

The design parameters for the CAD/CAM zirconia superstructure to be used on CoCr Base are identical to those cleared in K222288:
Minimum wall thickness – 0.4 mm
Minimum post height for single-unit restorations (length above the abutment collar/gingival height) – 4.5 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
All zirconia superstructures are for straight abutments only.

Pre-Milled Blank Abutments are available in engaging designs only. All patient-specific custom abutment fabrication for Pre-Milled 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 Pre-Milled Blank Abutments have a maximum (before milling) diameter of 10 mm or 14 mm, and are provided in a solid cylindrical design and with a pre-milled angled screw-channel design. The Pre-Milled Blank Abutments are manufactured from titanium alloy (Ti 6Al-4V) and from Co-Cr-Mo alloy (for MIS Seven and MIS M4 implants). The subject device Pre-Milled Blank Abutments are similar to Pre-Milled Blank Abutments cleared in K222288 and K222269

The design parameters for the CAD-CAM fabrication of custom abutments from Pre-Milled Blank Abutments are identical to those cleared in K222288 and K222269:
Minimum wall thickness – 0.45 mm
Minimum post height for single-unit restoration (length above the abutment collar/gingival height) – 4.0 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
Maximum angulation – refer to **Table 4** ***Pre-Milled Blank Abutments***.

Table 4 – Pre-Milled Blank Abutments

Compatible Implant System	Compatible Body Diameter, mm	Compatible Implant Platform Name	Maximum Angulation
Astra Tech EV	3.0	3.0	0°
	3.6	3.6	0°
	4.2	4.2	0°

Compatible Implant System	Compatible Body Diameter, mm	Compatible Implant Platform Name	Maximum Angulation
BioHorizons Internal	3.0, 3.4, 3.8	3.0	30°
	3.8, 4.2, 4.6	3.5	30°
	4.6, 5.2, 5.8	4.5	30°
	5.8, 7.0, 8.0	5.7	30°
Keystone/Paltop			
PrimaConnex Prima Plus	3.3, 3.5	3.5	30°
	4.0, 4.1	4.1	30°
	5.0	5.0	30°
Genesis	3.8, 3.5	3.5/3.8	30°
	4.5	4.5	30°
	5.5, 6.5	5.5/6.5	30°
Molaris Tilobemaxx	7	5.7	30°
	8	6.5	30°
	9	7.5	30°
Molaris I-Hexmrt	7	5.7	30°
	8	6.5	30°
	9	7.5	30°
Paltop Advanced Classic	3.25	NP (3.25)	30°
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)	30°
Paltop Advanced Plus	3.0, 3.25	NP (3.25)	30°
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)	30°
	6.0	WP (6.0)	30°
Paltop Dynamic	3.0, 3.25	NP (3.25)	30°
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)	30°
	6.0	WP (6.0)	30°
Paltop PAI Paltop PAI TC	3.25	NP (3.25)	30°
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)	30°
	6.0	WP (6.0)	30°
Paltop Dynamic Conical Paltop Conical Active PCA	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)	30°
MIS Seven MIS M4	3.3	NP (3.1)	0°
	3.75, 4.2	SP (3.5)	0°
	5.0, 6.0	WP (4.5)	0°
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM	0°
NobelActive® NobelReplace Conical NobelParallel Conical	3.0	3.0	0°
	3.5, 3.75	NP (3.5)	0°
	4.3, 5.0	RP (3.9)	0°
Osstem® TS Hiossen® ET	3.5	Mini	0°
	4.0, 4.5, 5.0, 55, 6.0, 7.0	Regular	0°
Straumann® BLX	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	RB/WB, WB	0°
Straumann® Bone Level	3.3	NC	0°
	4.1, 4.8	RC	0°
Zimmer Screw-Vent® Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5	0°
	4.7	4.5	

Multi-Unit Abutments are designed for attachment of multi-unit screw-retained restorations and are provided in three (3) designs, straight, angled 17°, and angled 30°. The designs are similar to that of Multi-Unit Abutments

cleared in K233316, K222288, and K222269. The Multi-Unit Abutments are manufactured from titanium alloy (Ti-6Al-4V).

The straight Multi-Unit Abutments are provided for MIS Seven and MIS M4 implants with SP (3.5), and WP (4.5) platforms, and for Neodent implants with the GM platform. The straight Multi-Unit Abutments have a non-engaging, threaded design that attaches directly to the implant. Straight Multi-Unit Abutments are provided with a prosthetic platform diameter of 4.8 mm, and with a gingival height ranging from 0.8 mm to 5.5 mm.

The angled Multi-Unit Abutments are provided for NobelReplace (Internal Tri-Channel) implants with NP (3.5) and RP (4.3) platforms. The angled Multi-Unit Abutments are provided only in a non-engaging design that requires an abutment screw. The Multi-Unit Abutments angled 17° are provided with a prosthetic platform diameter of 4.8 mm, and with a gingival height of either 2 mm or 3 mm. The Multi-Unit Abutments angled 30° are provided with a prosthetic platform diameter of 4.8 mm, and with a gingival height of either 4 mm or 5 mm.

DESSLoc Abutments are designed for overdenture attachment to attach directly to the implant. DESSLoc Abutments are made of titanium alloy (Ti-6Al-4V, and have a zirconium nitride (ZrN) coating, 2 μm to 3 μm thick, produced by a physical vapor deposition (PVD) process.

DESSLoc Abutments are provided only for MIS Seven and M4 implants with SP (3.5) and WP (4.5) platforms. Except for the implant connection, the design, material, and coating for the subject device DESSLoc Abutments are identical to those of the DESSLoc Abutments cleared in K222269.

DESS Dental Smart Solutions Screws are designed to attach the abutment to the implant or the prosthesis to the abutment. There are a total of eighteen (18) subject device screws compatible with the subject device components or previously cleared components. The new screws have designs that are similar to those of screws cleared in K233316, K222288, and K222269. Screws are made of titanium alloy (Ti-6Al-4V) and are available with and without a DLC (Diamond-like Carbon) coating. DLC coating is a polycrystalline tungsten carbide/carbon and chromium coating that is identical to the DLC coating on screws cleared in K233316, K222288, and K222269.

OEM IMPLANT COMPATIBILITY

To ensure that the subject abutments and screws are designed to fit the corresponding OEM implants, the dimensions and tolerances of subject abutments and screws have been established by reverse engineering dimensional analysis (of OEM implant bodies, OEM abutments, and OEM abutment screws) or by a contractual agreement and working relationship between Terrats Medical SL and the OEM implant manufacturer. For the subject cover screws and Multi-Unit Abutment screws for the DESS Active and Bone Level Implants, this analysis is not necessary for the Sponsor's own implant bodies. For all OEM compatibilities, except for the MIS implant lines, the reverse engineering analysis or contractual agreement information was provided in prior Terrats Medical 510(k) submissions. For the MIS implant lines, the reverse engineering analysis is provided in this submission. The confirmation of compatibility is summarized in the following **Table 5** ***Compatible Implant Systems Confirmation of Compatibility***.

Table 5 – Compatible Implant Systems Confirmation of Compatibility

Implant Compatibility (Connection)	Implant Body Diameter, mm	Implant Platform, mm	Terrats Medical 510(k) Containing Reverse Engineering or OEM Contractual Agreement
Astra Tech EV (Internal Taper)	3.0	3.0	K212628
	3.6	3.6	K191986
	4.2	4.2	
	4.8	4.8	
Astra Tech OsseoSpeed TX (Internal Taper)	3.0	3.0	K191986
	3.5, 4.0	3.5/4.0	K170588
	4.5, 5.0	4.5/5.0	

Implant Compatibility (Connection)	**Implant Body Diameter, mm**	**Implant Platform, mm**	**Terrats Medical 510(k) Containing Reverse Engineering or OEM Contractual Agreement**
BioHorizons Internal (Internal Hex)	3.0, 3.4, 3.8	3.0	K212628
	3.8, 4.2, 4.6	3.5	
	4.6, 5.2, 5.8	4.5	
	5.8, 7.0, 8.0	5.7	
Biomet 3i OSSEOTITE® (External Hex)	3.25	3.4	K170588
	3.75, 4.0	4.1	
	5.0	5.0	
Dentium SuperLine (Internal Taper)	3.6, 4.0, 4.5, 5.0, 6.0, 7.0	3.3	K222288
DESS Active (Internal Conical)	3.0	3.0	K212538 (Sponsor's own implants)
	3.5	NP	
	4.3, 5.0	RP	
	5.5	WP	
DESS Bone Level (Internal Conical)	3.3	NC	
	4.1, 4.8	RC	
PrimaConnex Prima Plus (Internal TiLobe)	3.3, 3.5	3.5	K222269
	4.0, 4.1	4.1	
	5.0	5.0	
Genesis (Internal TiLobe)	3.5, 3.8	3.5/3.8	K222269
	4.5	4.5	
	5.5, 6.5	5.5/6.5	
Molaris Tilobemaxx (Internal TiLobe)	7	5.7	K222269
	8	6.5	
	9	7.5	
Molaris I-Hexmrt (Internal Hex)	7	5.7	K222269
	8	6.5	
	9	7.5	
Paltop Advanced Classic (Internal Hex)	3.25	NP (3.25)	K222269
	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)	K222269
	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)	K222269
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)	
	6.0	WP (6.0)	
Paltop PAI Paltop PAI TC (Internal Hex)	3.25	NP (3.25)	K222269
	3.75, 4.2, 5.0	SP (3.75/4.2/5.0)	
	6.0	WP (6.0)	
Paltop Dynamic Conical Paltop Conical Active (PCA) (Internal Conical)	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)	K222269
MIS Seven MIS M4 (Internal Hex)	3.3	NP (3.1)	This Submission
	3.75, 4.2	SP (3.5)	
	5.0, 6.0	WP (4.5)	
Neodent (Morse taper GM)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM	K212628

Implant Compatibility (Connection)	Implant Body Diameter, mm	Implant Platform, mm	Terrats Medical 510(k) Containing Reverse Engineering or OEM Contractual Agreement
NobelActive® NobelReplace Conical NobelParallel Conical (Conical Connection)	3.0	3.0	K191986
	3.5, 3.75	NP (3.5)	K170588
	4.3, 5.0	RP (3.9)	
	5.5	WP (5.1)	K191986
NobelReplace (Internal Tri-channel)	3.5	NP (3.5)	K170588
	4.3	RP (4.3)	
Osstem® TS Hiossen® ET	3.5	Mini	K191986
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular	
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5	RB	K212628
	5.0, 5.5, 6.5	WB	
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC	K170588
	4.1, 4.8	RC	
Zimmer Screw-Vent® Tapered Screw-Vent® (Internal Hex)	3.3, 3.7, 4.1	3.5	K170588
	4.7	4.5	
TSX™ Implant System (Internal Hex)	3.7, 4.1, 4.7	3.5	K231434

MATERIALS

The subject device abutments are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 or from Co-Cr-Mo alloy conforming to ASTM F1537. The subject device screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136. Abutments are colored gold by an anodization process that is identical to that used on abutments cleared in K233316, K222288, and K222269. Ti Base Abutments and AURUM Base Abutments have a SelectGrip® surface to aid in bonding retention that is identical to that used on abutments cleared in K233316, K222288, and K222269, Screws are available with and without a DLC (Diamond-like Carbon) coating. The DLC coating is a polycrystalline tungsten carbide/carbon and chromium coating that is identical to the DLC coating on screws cleared in K233316, K222288, and K222269.

PERFORMANCE DATA

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

- provided in this submission was non-clinical analysis to evaluate the subject devices (including all abutments, abutment screw, and materials) 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;
- provided in this submission was reverse engineering dimensional analysis (of OEM implant bodies, OEM abutments, and OEM abutment screws) to demonstrate that the subject device abutments are compatible with the MIS Seven and MIS M4 implants;
- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device Pre-Milled Blank Abutments compatible with BioHorizons Internal (Internal Hex connection) implants, the PrimaConnex (Internal TiLobe connection) implants, Paltop Dynamic (Internal Hex connection) implants, and Paltop Dynamic Conical (Internal Conical connection) implants;

- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device Ti Base Abutments compatible with Biomet 3i OSSEOTITE implants, the PrimaConnex (Internal TiLobe connection) implants, Paltop Dynamic (Internal Hex connection) implants, and Paltop Dynamic Conical (Internal Conical connection) implants;
- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device Multi-Unit Abutments compatible with Nobel Replace (Internal Tri-channel connection) implants;
- referenced from K233316 was moist heat sterilization for subject devices provided non-sterile to the end user, validated to a sterility assurance level of 10^{-6} by the overkill method according to ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2; analysis showed that the subject devices do not create a new worst case for moist heat sterilization;
- referenced from K233316 was gamma irradiation sterilization validation to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VDmax25, according to ISO 11137-1 and ISO 11137-2; bacterial endotoxin testing including *Limulus* amebocyte lysate (LAL) test according to ANSI/AAMI ST72 to demonstrate that all sterile product meets a limit of < 20 EU/device; and shelf life testing of samples after accelerated aging equivalent to five (5) years of real time aging according to ASTM F1980, with testing of the packaging sterile barrier and sterility testing of product.

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 K233316, and the reference devices K222288 and K222269. 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. Except for the list of compatible OEM implants and sizes, the Indications for Use Statement (IFUS) for the subject device is substantially equivalent to that of K233316, K222288, and K222269.

The lists of the specific OEM implant compatibilities in the IFUS differ between the subject device and the primary predicate and the reference devices. The other minor difference is that the IFUS for the subject device includes language regarding digital design and validated milling centers; the IFUS for the primary predicate K233316 does not include the language regarding CAD-CAM abutments or a validated milling center. The IFUS for the reference devices K222288 and K222269 include the language regarding CAD-CAM abutments and a validated milling center.

The primary predicate device K233316 and the reference devices K222288 and K222269 are in support of substantial equivalence of the subject device designs, material, manufacturing, and biocompatibility.

All subject device abutments and screws are similar or identical in designs, materials, and technological characteristics to corresponding abutments of the primary predicate device K233316 and the reference devices K222288 and K222269. The subject submission, K233316, K222288, and K222269 all include abutments manufactured from Ti-6Al-4V alloy conforming to ASTM F136. Abutments are anodized by a process that is identical to that used on abutments cleared in K233316. Ti Base Abutments and AURUM Base Abutments have a SelectGrip® surface to aid in bonding retention that is identical to the surface used on abutments cleared in K233316. Abutments screws manufactured from Ti-6Al-4V alloy are available with and without a DLC (Diamond-like Carbon) coating that is identical to the DLC coating on screws cleared in K233316. The subject submission and K222288 also include abutments manufactured from Co-Cr-Mo alloy conforming to ASTM F1537.

The subject device abutments and abutment screws have similar or identical ranges of abutment-implant platform diameter, prosthetic platform diameter, and angulation as the components cleared in K233316, K222288, and K222269. The subject device abutments and the reference device K212628 include abutments compatible with the

Nobel Biocare conical connection implants (NobelActive®, NobelReplace Conical, NobelParallel Conical) with the 3.0 mm body/platform diameter.

Selected subject device components are provided sterile by gamma irradiation and are packaged in a PETG blister with a Tyvek® lid. This is the same sterilization, packaging, and 5-year shelf life that was referenced in the primary predicate K233316. For the subject devices provided non-sterile, the previously validated moist heat cycle, referenced from the primary predicate and reference devices is applicable to the non-sterile subject devices.

The risks associated with use of the subject device abutments with angulation (Ti Bases, Pre-Milled Blanks, and Angled Multi-Unit Abutments) in combination with the compatible implants are mitigated by the mechanical testing provided in the *Bench Testing* attachment to this submission.

CONCLUSION

Any differences in the technological characteristics between the subject device, the predicate device, and reference devices do not raise different questions of safety or effectiveness. The data included in this submission demonstrate substantial equivalence to the predicate and reference devices listed above.

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

- have the same intended use,
- use the same operating principles,
- incorporate the same basic designs,
- incorporate the same or very similar materials, and
- have similar packaging and are sterilized using the same materials and processes.

The basis for the belief of Terrats Medical SL that the subject device is substantially equivalent to the predicate devices is summarized in the following **Table 6, *Substantial Equivalence***.

Table 6 – Substantial Equivalence

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	K240208 DESS Dental Smart Solutions Terrats Medical SL	K233316 DESS Dental Smart Solutions Terrats Medical SL	K222288 DESS Dental Smart Solutions Terrats Medical SL	K222269 DESS Dental Smart Solutions Terrats Medical SL
Product Code	NHA	NHA	NHA	NHA
Reason for predicate/reference	n/a	Abutment designs, OEM compatibilities, materials, manufacturing, biocompatibility	Abutment designs, OEM compatibilities, materials, manufacturing, biocompatibility	Abutment designs, OEM compatibilities, materials, manufacturing, biocompatibility
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
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 Ti Base abutments or Pre-Milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the Device Description attachment in this submission.*	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. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K233316.*	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 Ti Base abutments or Pre-Milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K222288.*	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. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K222269.*
Designs	Healing Abutments	Healing Abutments	Healing Abutments	
	Temporary Abutments	Temporary Abutments	Temporary Abutments	
	Ti Base Abutments		Ti Base Abutments	Ti Base Abutments
	AURUM Base Abutments			AURUM Base Abutments
	CoCr Base Abutments		CoCr Base Abutments	
	Pre-Milled Blank Abutments		Pre-Milled Blank Abutments	Pre-Milled Blank Abutments
	Multi-unit Abutments, Straight	Multi-unit Abutments, Straight	Multi-unit Abutments, Straight	Multi-unit Abutments, Straight
	Multi-unit Abutments, Angled 17° and 30°	Multi-unit Abutments, Angled 17° and 30°	Multi-unit Abutments, Angled 17° and 30°	Multi-unit Abutments, Angled 17° and 30°
	DESSLoc Abutments		DESSLoc Abutments	DESSLoc Abutments
	Screws	Screws	Screws	Screws
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
Abutment/Implant Platform Ø, mm	3.0 – 7.5	2.52 – 5.7	2.52 – 6.5	3.25 – 7.5
Prosthetic Platform Ø, mm	3.5 – 7.0	4.5 – 6.8	4.5 – 6.5	4.1 – 7.0
Abutment Angle	0° – 30°	0°, 17°, 30°	0°, 17°, 30°	0°, 17°, 30°
Materials				
Abutment Material	Ti-6Al-4V (ASTM F136) Co-Cr-Mo (ASTM F1537)	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V alloy (ASTM F136) Co-Cr-Mo (ASTM F1537)	Ti-6Al-4V (ASTM F136)
Abutment Surface	Anodization SelectGrip® surface Zirconium nitride (ZrN)	Anodization SelectGrip® surface	Anodization SelectGrip® surface Zirconium nitride (ZrN)	Anodization SelectGrip® surface Zirconium nitride (ZrN)
Superstructure Material	Zirconia (Y-TZP)		Zirconia (Y-TZP)	Zirconia (Y-TZP)
Screw Material	Ti-6Al-4V alloy DLC coating	Ti-6Al-4V alloy DLC coating	Ti-6Al-4V alloy DLC coating	Ti-6Al-4V alloy DLC coating
How Provided				
Sterilization	Sterile by gamma irradiation, and Non-sterile	Sterile by gamma irradiation, and Non-sterile	Non-sterile	Non-sterile
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use