



Terrats Medical SL
% Melissa Burbage
Principal Regulatory Consultant
Enerxen Consulting, Inc.
1155 Metcalfe Street, Suite 1572
Montreal, PQ H3B2V6
CANADA

May 22, 2025

Re: K250639

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, PNP
Dated: February 28, 2025
Received: March 3, 2025

Dear Melissa Burbage:

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

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

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

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

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

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

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

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

Sincerely,

Andrew I. Steen -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K250639

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 Pre-milled Blanks are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Implant Platform Name
Ankylos C/X	3.5, 4.5, 5.5	3.5, 4.5, 5.5
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 Internal	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	3.3	3.3
	3.8	3.8
	4.3	4.3
	5.0	5.0
Friadent XiVE®	3.4	3.4
	3.8	3.8
	4.5	4.5
	5.5	5.5
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive® NobelReplace/ NobelParallel Conical	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
	5.5	WP
NobelReplace® Trilobe	3.5	NP
	4.3	RP
	5.0	WP
	6.0	6.0
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
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
	3.3, 4.1, 4.8	RN
	4.8	WN

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

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

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary
Terrats Medical SL
DESS® Dental Smart Solutions
K250639

May 22, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda 75-99 Barberà del Vallès 08210 Barcelona, Spain Telephone: +34 935 646 006 Fax: +34 935 647 317
Official Contact	Roger Terrats, CEO
Representative/Consultant	Melissa Burbage Enerxen Consulting, Inc. 1155 Metcalfe Street, Suite 1572 Montreal, Quebec H3B 2V6 Telephone: +1 619-480-7733 Email: melissa.burbage@enerxen.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
Primary Product Code	NHA
Secondary Product Code	PNP
Classification Panel	Dental Products Panel
Reviewing Division	DHT1B: Division of Dental Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device

K221301, DESS Dental Smart Solutions, Terrats Medical SL

Additional Predicate Device

K240982, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices

K171876, Amann Ceramill Zolid Gen-X and Zolid Bion
K190079, ArgenZ HT+
K190079, ArgenZ HT+ML
K071410, ArgenZ Ultra
K141724, Zirlux 16+
K152175, Zirlux Anterior Multi
K110719, Zirlux Transitions
K180703, VITA YZ ST and VITA YZ XT, VITA Zahnfabrik H.Rauter GmbH. Co.
K130436, Multilink Hybrid Abutment Cement, Ivoclar Vivadent AG
K151455, 3Shape Abutment Designer Software, 3Shape A/S
K193352, AbutmentCAD, exocad GmbH

K140347, Ankylos C/X Implant System, DENTSPLY International, Inc.
K111287, Astra Tech Implant System, Astra Tech AB
K120414, OsseoSpeed Plus, Astra Tech AB
K101732, OsseoSpeed™ Astra Tech ABK042429, The Prodigy System Dental Implants, BioHorizons Implants System, Inc.
K071638, BioHorizons Tapered Internal Implant System, BioHorizons Implants System, Inc.
K063341, 3i OSSEOTITE Certain® Dental Implants, Implant Innovations, Inc.
K063286, OSSEOTITE® Dental Implants, Implant Innovations, Inc.
K083496, Camlog Implant System, Altatech GmbH
K073075, Friadent Implant Systems, DENTSPLY International, Inc.
K110955, AnyRidge Internal Implant System, Megagen Co., Ltd.
K163194, Neodent Implant System – GM Line, JJGC Industria E Comercio De Materials Dentarios SA
K142260, NobelActive®, Nobel Biocare AB
K102436, NobelActive 3.0, Nobel Biocare AB
K073142, NobelReplace Hexagonal Implants, Nobel Biocare AB
K050705, TiUnite Implants, Nobel Biocare AB
K050406 NobelSpeedy Implants, Nobel Biocare AB
K022562, Various Brånemark System Implants–Immediate Function Indication, Nobel Biocare AB
K161604, Osstem Implant System, OSSTEM IMPLANT Co., Ltd
K173961, Straumann BLX Implant System, Institut Straumann AG
K140878, Straumann® Bone Level Tapered Implants, Straumann USA, LLC
K130222, Straumann® Dental Implant System SLActive and Roxolid Product Families, Straumann USA, LLC
K011028, Screw-Vent Dental Implant System, Sulzer Dental, Inc.
K112160, Tapered Screw-Vent® X Implant, Zimmer Dental, Inc.

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 Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Implant Platform Name
Ankylos C/X	3.5, 4.5, 5.5	3.5, 4.5, 5.5
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 Internal	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	3.3	3.3
	3.8	3.8
	4.3	4.3
	5.0	5.0
Friadent XiVE®	3.4	3.4
	3.8	3.8
	4.5	4.5
	5.5	5.5
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive® NobelReplace/ NobelParallel Conical	3.0	3.0
	3.5	NP
	4.3, 5.0	RP
	5.5	WP
NobelReplace® Trilobe	3.5	NP
	4.3	RP
	5.0	WP
	6.0	6.0
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
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
	3.3, 4.1, 4.8	RN
	4.8	WN
Zimmer Screw-Vent® / Tapered Screw-Vent®	3.3, 3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the DESS Dental Smart Solutions abutment system cleared under K221301 and K240982 to allow additional options of zirconia material, scanners, CAM software, and milling machines to the digital dentistry workflow. The subject devices are to be sent to Terrats Medical validated milling centers for manufacture, or to be designed and manufactured via a digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, titanium and ceramic material, milling machine, and associated tooling and accessories. There are no changes to the abutment design, implant compatibilities, or design parameters. All part numbers have been cleared for manufacturing via a validated milling center and digital dentistry workflows (also referred to as point of care) under K221301 and K240982.

The subject device DESS Dental Smart Solutions abutments provide a range of prosthetic solutions for dental implant restoration. DESS abutments are offered in a variety of connection types to enable compatibility with currently marketed dental implants. All abutments are provided non-sterile, and each abutment is supplied with the appropriate abutment screw (if applicable) for attachment to the corresponding implant.

Subject device Base Abutments are designed for fabrication of a patient-specific CAD/CAM zirconia superstructure on which a crown may be placed. They are two-piece abutments for which the second part (or top half) is the ceramic superstructure. They also may be used for support of a crown directly on the abutment.

All patient-specific custom abutment fabrication for Base Abutments and Pre-milled (Blank) Abutments is by prescription on the order of the clinician. The subject device Pre-milled (Blank) Abutments and all zirconia superstructures for use with the subject device Ti Base Interface, DESS Aurum Base, ELLIPTIBase, and DESS C-Base will be manufactured using a validated milling center or a digital dentistry workflow. A validated milling center will be under FDA quality system regulations. The digital dentistry workflow scans files from intra-oral and lab (desktop) scanners, CAD software, CAM software, titanium and ceramic material, milling machine and associated tooling and accessories.

The digital dentistry workflow uses scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The digital workflow includes the following products:

Workflow Step	Material/Equipment
Zirconia Material for Ti-Base	VITA YZ ST and VITA YZ XT (K180703)
	Amann Ceramill Zolid Gen-x (K171876)
	Amann Ceramill Zolid Bion (K171876)
	ArgenZ HT+ (K190079)
	ArgenZ HT+ML (K190079)
	ArgenZ Ultra (K071410)
	Zirlux 16+ (K141724)
	Zirlux Anterior Multi (K152175)
	Zirlux Transitions (K110719)
Cement for Ti-Base	Ivoclar Vivadent Multilink Hybrid Abutment Cement
Titanium Material	Titanium alloy conforming to ASTM F136
Scanners (exempt per 872.3661)	3Shape D2000 Dental Lab 3D Scanner
	3Shape TRIOS Intraoral Scanner
	3Shape E-series Desktop Scanner
	3Shape D900 Dental Lab Scanner
	Dexis IOS Intraoral Scanner
	Medit i700 Intraoral Scanner
	Medit T500 3D Dental Scanner
	Primescan Intraoral Scanner
CAD Design	3Shape Abutment Designer Software
	AbutmentCAD (exoCAD)
CAM Software	Ceramill Match 2
	DentalCAM
	hyperDENT CAM Software
	MillBox
Milling Machine	Arum 500
	Arum 5X-200
	Ceramill Matron
	Dyamach AS1
	Imes CORITEC 350i
	DGShape DWX-52D
	DGShape DWX-53D
	Versamil AX200
	Versamil AX314DW
	Versamil AX500 & AX500L
	Versamil AX726DW & AX726DWPRO
	VHF E5
	VHF K5+
	VHF N4+
	VHF R5
	VHF S5
	VHF Z4

The design parameters for the CAD/CAM zirconia superstructure to be used on Base Abutments:

Minimum wall thickness – 0.4 mm

Minimum post height for single-unit loading

Ti Base Interface – 4.2 mm

DESS Aurum Base – 4.0 mm

ELLIPTIBase – 4.0 mm

C-Base – 4.7 mm

Minimum gingival height – 0.5 mm

Maximum gingival height – 6.0 mm

All zirconia superstructures are for straight abutments only.

By definition, the abutment post height is considered by FDA to be the “stump” portion above the gingival collar, to which the restorations attach.

The design parameters for the CAD/CAM Pre-Milled Blank custom abutments:

- Minimum wall thickness – 0.4 mm
- Minimum post height – 4.0 mm
- Maximum gingival height – 6.0 mm
- Minimum gingival height – 0.5 mm
- All Pre-Milled Blank are for straight abutments only.

By definition, the abutment post height is considered by FDA to be the “stump” portion above the gingival collar, to which the restorations attach.

For the CAD/CAM Pre-milled Blanks that are compatible with Astra Tech EV (except for 3.0 mm implants), Astra Tech OsseoSpeed (except for 3.0), Biomet 3i Certain, Neodent Grand Morse, Nobel Active/NobelParallel Conical (except for 3.0 mm implants), NobelReplace Trilobe, Nobel Brånemark, Straumann Bone Level, Straumann BLX, and Zimmer Screw-Vent/Tapered Screw-Vent, the following design parameters may be used:

- Minimum wall thickness – 0.45 mm
- Minimum post height – 4.0 mm
- Maximum gingival height – 6.0 mm
- Minimum gingival height – 0.5 mm
- Maximum angulation of the final abutment - 30°

By definition, the abutment post height is considered by FDA to be the “stump” portion above the gingival collar, to which the restorations attach.

For the CAD/CAM Pre-milled Blanks that are compatible Nobel Active/NobelParallel Conical 3.0 mm implants, the following design parameters may be used:

- Minimum wall thickness – 0.45 mm
- Minimum post height – 4.0 mm
- Maximum gingival height – 3.0 mm
- Minimum gingival height – 0.5 mm
- Maximum angulation of the final abutment - 30°

By definition, the abutment post height is considered by FDA to be the “stump” portion above the gingival collar, to which the restorations attach.

Screws

DESS Dental Smart Solutions screws are designed to attach the abutment to the implant or the prosthesis to the abutment. The screws were cleared in K170588, K173908, K191986, K203464, K212577, and K212628. There have been no changes to the screws and there are no new subject device screws. Screws are available with and without a DLC (Diamond-like Carbon) coating.

Summary of Subject Device Components and Implant Platforms for Compatible Implant Systems

Compatible Implant Systems	DESS Abutment System	Ti Base Interface	DESS Aurum Base	ELLIPTI-Base	DESS C-Base	Pre-milled Blank Ti	Screws
Ankylos C/X	Internal Ank	3.5, 4.5, 5.5			3.5, 4.5, 5.5	3.5, 4.5, 5.5	X
Astra Tech EV	Conic EVO	3.0, 3.6, 4.2, 4.8, 5.4	3.6, 4.2, 4.8	3.0	3.6, 4.2, 4.8	3.0, 3.6, 4.2, 4.8, 5.4	X
Astra Tech OsseoSpeed	Internal Hex Conic	3.0, 3.5/4.0, 4.5/5.0	3.5/4.0, 4.5/5.0		3.5/4.0, 4.5/5.0	3.0, 3.5/4.0, 4.5/5.0	X
BioHorizons Internal	BH Internal	3.0, 3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.0		3.5, 4.5, 5.7	X
Biomet 3i Certain	Internal Hex Click	3.4, 4.1, 5.0	3.4, 4.1, 5.0		3.4, 4.1, 5.0	3.4, 4.1, 5.0	X
Biomet 3i OSSEOTITE	External Hex USA	3.4, 4.1, 5.0	3.4, 4.1, 5.0		3.4, 4.1, 5.0	3.4, 4.1, 5.0	X
Camlog	Internal CAM	3.3, 3.8, 4.3, 5.0	3.8, 4.3			3.3, 3.8, 4.3, 5.0	X
Frident XiVE	Internal Hex FD	3.4, 3.8, 4.5, 5.5	3.4, 3.8, 4.5		3.4, 3.8, 4.5, 5.5	3.8, 4.5, 5.5	X
Neodent Grand Morse	Neo GM	Grand Morse	Grand Morse			Grand Morse	X
NobelActive, NobelParallel Conical	Active Hex	3.0, NP, RP, WP	NP, RP	3.0	NP, RP, WP	3.0, NP, RP, WP	X
NobelReplace Trilobe	Tri-lobe	NP, RP, WP, 6.0	NP, RP, WP		NP, RP, WP, 6.0	NP, RP, WP, 6.0	X
Nobel Brånemark System	External Hex Universal	NP, RP, WP	NP, RP		NP, RP	NP, RP, WP	X
Osstem TS	Conic OSS	Mini, Regular	Mini, Regular		Mini, Regular	Mini, Regular	X
Straumann BLX	Conical BLX	RB/WB, WB	RB/WB, WB			RB/WB, WB	X
Straumann Bone Level	Conical BL	NC, RC	NC, RC	NC	NC, RC	NC, RC	X
Straumann Tissue Level	Octagon	NNC, RN, WN	RN, WN	NNC	RN, WN	NNC, RN, WN	X
Zimmer Screw Vent / Tapered Screw Vent	Internal Hex USA	3.5, 4.5, 5.7	3.5, 4.5, 5.7	3.5	3.5, 4.5, 5.7	3.5, 4.5, 5.7	X

MATERIAL COMPOSITION

Zirconia is the material required for superstructures on Ti Base Interface, DESS Aurum Base and ELLIPTI-Base, and C-Base with the base portion 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)*. The cement required in labeling for bonding of superstructures to the base is Multilink Hybrid Abutment Cement from Ivoclar Vivadent AG, cleared under K130436. There have been no changes to the required cement material, processing, or handling, as cleared in K221301 and K240982.

Zirconia is the material required for superstructures. The zirconia materials have all been cleared by FDA and are conforming to ISO 6872 *Dentistry – Ceramic Materials*.

- Amann Ceramill Zolid Gen-X, cleared in K171876
- Amann Ceramill Zolid Bion, cleared in K171876
- Argen ArgenZ HT+, cleared in K190079
- Argen ArgenZ HT+ ML, cleared in K190079
- Argen ArgenZ Ultra, cleared in K071410
- VITA YZ ST, cleared in K180703
- VITA YZ XT, cleared in K180703
- Zahn Zirlux 16+, cleared in K141724

- Zahn Zirlux Anterior Multi, cleared in K152175
- Zahn Zirlux Transitions, cleared in K110719

All subject device pre-milled blanks, base, and 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)* or from Co-Cr-Mo alloy conforming to ASTM F1537 *Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)*. There have been no changes in material, processing, or handling of the bases and screws. These products are treated with the same surface treatments (SelectGrip surface, anodization, and DLC coating) and are manufactured in the same or similar facilities using the same or similar manufacturing processes as used for the Terrats Medical components previously cleared in K221301 and K240982.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included the following: Sterilization validation according to ISO 17665-1, ISO 17665-2, and ISO 14937; biocompatibility testing according to ISO 10993-5 and ISO 10993-12; validation testing of the CAM restriction zones; fatigue testing and reverse engineering analysis of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility were leveraged from K221301 and K240982; MR Conditional labeling; and validation testing of the CAD design restrictions were leveraged from K221301 and K240982. Fatigue testing of OEM implant bodies with patient specific abutments made at worst-case angled conditions. Software verification included testing of restrictions that prevent design of components outside of the stated design parameters. In addition, the abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified by the user. To address the potential risk of damage to the implant-abutment connection geometry during the milling of the patient-matched portions of the abutment blanks, validation testing of the CAM restriction zones was conducted, including verification to show avoidance of damage or modifications of the connection geometry, and locking of restriction zones from user editing in the CAM software. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

Subject device abutments are identical to the predicate device K221301 and K240982. Both are intended for use with endosseous dental implants to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. Both have the same compatible OEM implants. Both indicate manufacturing using a validated milling center or to be designed and manufactured using a digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories.

All subject device abutments (base and blanks) and screws are equivalent in design, materials and technological characteristics to those of the predicate device K221301 and K240982. There are no changes to the abutment designs or implant compatibilities. The material of the abutment and superstructure is equivalent to the predicate device K221301 and K240982. All part numbers and design parameters have been cleared within previous submissions cleared for manufacturing via a validated milling center and digital dentistry workflow.

CONCLUSION

The subject device, the predicate device, and reference devices have the same intended use, technological characteristics, and are made of the same materials. The subject device, the predicate device, and reference devices encompass the same range of physical dimensions, manufactured by similar methods, 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.

Device Comparison Table

Comparison	Subject Device	Predicate Devices	Predicate Devices
	DESS Dental Smart Solutions Terrats Medical SL	K240982 DESS Dental Smart Solutions Terrats Medical SL	K221301 DESS Dental Smart Solutions Terrats Medical SL
Product Code	NHA, PNP	NHA, PNP	NHA, PNP
Reason for predicate/reference	n/a	n/a	n/a
Intended Use	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function
Indications	DESS Dental Smart Solutions abutments are intended for dental prosthetic restorations. DESS Dental Smart Solutions abutments are used as an interface between a dental implant or dental abutment and a dental restoration and will be attached to the implant or abutment using a prosthetic screw and attached to the dental restoration by cementing. All digitally designed custom abutments for use with Base abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories. <i>For complete Indications for Use statement on OEM Compatibility see Section 4.</i>	DESS Dental Smart Solutions abutments are intended for dental prosthetic restorations. DESS Dental Smart Solutions abutments are used as an interface between a dental implant or dental abutment and a dental restoration and will be attached to the implant or abutment using a prosthetic screw and attached to the dental restoration by cementing. All digitally designed custom abutments for use with Base abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories. <i>For complete Indications for Use statement on OEM Compatibility see Section 4.</i>	DESS Dental Smart Solutions abutments are intended for dental prosthetic restorations. DESS Dental Smart Solutions abutments are used as an interface between a dental implant or dental abutment and a dental restoration and will be attached to the implant or abutment using a prosthetic screw and attached to the dental restoration by cementing. All digitally designed custom abutments for use with Base abutment or Pre-milled Blank are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories. <i>For complete Indications for Use statement on OEM Compatibility see Section 4.</i>
Design			
Abutment Designs	CAD/CAM Bases, CAD/CAM Blanks	CAD/CAM Bases, CAD/CAM Blanks	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 Ø, mm	2.52 – 6.5	2.52 – 6.5	2.52 – 6.5
Abutment Angle	30° max* for Blanks 0° for TiBases	30° max* for Blanks 0° for TiBases	30° max* for Blanks 0° for TiBases
Material			
Abutment Material (Blanks)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Abutment Metallic Material (Bases)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)
Screw Material	Ti-6Al-4V ELI (ASTM F136) DLC coating	Ti-6Al-4V ELI (ASTM F136) DLC coating	Ti-6Al-4V ELI (ASTM F136) DLC coating
Superstructure Material (Bases)	Zirconia (ISO 6872)	Zirconia (ISO 6872)	Zirconia (ISO 6872)
Surface	Anodization and a SelectGrip® surface	Anodization and a SelectGrip® surface	Anodization and a SelectGrip® surface
Manufacturing	Digital Dentistry Workflow & Validated Milling Center	Digital Dentistry Workflow & Validated Milling Center	Digital Dentistry Workflow & Validated Milling Center

Comparison	Subject Device	Predicate Devices	Predicate Devices
	DESS Dental Smart Solutions Terrats Medical SL	K240982 DESS Dental Smart Solutions Terrats Medical SL	K221301 DESS Dental Smart Solutions Terrats Medical SL
Digital Design Workflow	3Shape Intraoral scanner Trios series, 3Shape E-series and D2000 Lab Scanner, Dexis IOS Intraoral Scanner, Medit i700 Intraoral Scanner, Medit Identica T300 3D Dental Scanner, Primescan Intraoral Scanner	3Shape Intraoral scanner Trios series, 3Shape E-series, 3Shape D900 Dental Lab Scanner, and D2000 Lab Scanner	3Shape Intraoral scanner Trios series, 3Shape E-series, 3Shape D900 Dental Lab Scanner, and D2000 Lab Scanner
	3Shape Abutment Designer Software (3Shape A/S) K151455, AbutmentCAD (exocad GmbH) K193352	3Shape Abutment Designer Software (3Shape A/S) K151455, AbutmentCAD (exocad GmbH) K193352	3Shape Abutment Designer Software (3Shape A/S) K151455
Digital Manufacturing Workflow	Ceramill Match 2, DentalCAM, hyperDent, MillBox	DentalCAM	DentalCAM
	Arum 5X-200, Arum 500, Ceramill Matron, Dyamach AS1, Imes CORITEC 350i, DGShape DWX-52D, DGShape DWX-53D, Versamil 5X200, Versamil AX314DW, Versamil 5X500, Versamil 5X500L, Versamil AX726DW, Versamil AX726DWPRO, VHF E5, VHF K5+, VHF N4+, VHF R5, VHF S5, VHF Z4	VHF R5	VHF R5

*30° for select OEM Connections as listed above in the Subject