July 23, 2025

Terrats Medical SL
% Rebecca Kattan
Regulatory Specialist
PaxMed International, LLC
1925 Palomar Oaks Way
Suite 210
Carlsbad, California 92008

Re: K251280
Trade/Device Name: DESS® Dental Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: April 24, 2025
Received: April 24, 2025

Dear Rebecca Kattan:

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

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)*
K251280

Device Name
DESS® Dental Implants

Indications for Use *(Describe)*

DESS® dental implants are indicated for surgical placement in the upper or lower jaw in edentulous or partially edentulous patients for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. They are designed to support single or multi-unit restorations in splinted or non-splinted applications, as well as to support overdenture attachment systems. DESS® dental implants may be used for immediate or early implantation following extraction or loss of natural teeth, and may be used for immediate or delayed loading techniques. Implants may be loaded immediately when good primary stability is achieved and occlusal loading is appropriate.

DESS® NEO GM Dental Implants are compatible with DESS® Dental Smart Solutions abutments having the identical NEO GM connection manufactured by Terrats Medical SL.

DESS® NEO GM Dental Implants with a diameter of 3.5 mm are indicated for use in reduced interdental spaces, where there is not enough alveolar bone for a larger diameter implant. The use of 3.5 mm implants is intended only for rehabilitation of the anterior region of the mouth.

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® Pre-Milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems for DESSLoc Abutments

Compatible Implant System (Connection)	**Implant Body Diameter, mm**	**Implant Platform Name**
Astra Tech EV (Internal Taper)	3.6	3.6
	4.2	4.2
	4.8	4.8
BioHorizons (Internal)	3.8, 4.2, 4.6	3.5
	4.6, 5.2, 5.8	4.5
MIS Seven MIS M4 (Internal Hex)	3.75 ,4.2	SP (3.5)
	5.0, 6.0	WP (4.5)
NobelActive® NobelReplace Conical NobelParallel Conical (Conical connection)	3.5, 3.75	NP (3.5)
	4.3, 5.0	RP (3.9)
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC
	4.1, 4.8	RC

Compatible Implant Systems for Pre-Milled Blank Abutments

Compatible Implant System (Connection)	**Implant Body Diameter, mm**	**Implant Platform Name**
Implant Active Konus Implant Classic Konus Implant Active Bio (Internal Taper)	3.3, 3.75, 4.2, 5.0, 6.0	2.8

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
K251280
Terrats Medical SL
DESS® Dental Implants

July 22, 2025

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda, 75-99 Barberà del Vallès 08210 Barcelona, Spain
Telephone	+34 935 646 006
Official Contact	Roger Terrats, CEO
Representative/Consultant	Rebecca E. Kattan, PhD Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 1925 Palomar Oaks Way, Suite 210 Carlsbad, CA 92008 Telephone +1 858-792-1235 Email rkattan@paxmed.com kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	DESS® Dental Implants
Common Name	Dental implant
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Secondary 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

Primary Predicate Device

K212538, DESS® Dental Implants, Terrats Medical SL

Reference Devices

K143353, Hahn Tapered Implant System, Prismatik Dentalcraft, Inc.
K242340, DESS Dental Smart Solutions, Terrats Medical SL
K212628, DESS Dental Smart Solutions, Terrats Medical SL
K240208, DESS Dental Smart Solutions, Terrats Medical SL
K222288, DESS Dental Smart Solutions, Terrats Medical SL
K191986, DESS Dental Smart Solutions, Terrats Medical SL

K170588, DESS Dental Smart Solutions, Terrats Medical SL
K243212, DESS Dental Smart Solutions, Terrats Medical SL
K233316, 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
K042429, BioHorizons The Prodigy System™ Endosseous Implants, BioHorizons Implant Systems, Inc.
K071638, BioHorizons Tapered Internal Implant System, BioHorizons Implant Systems, Inc.
K180282, MIS Internal Hex Dental Implant System, MIS Implants Technologies Ltd.
K142260, NobelActive®, Nobel Biocare AB
K173418, NobelParallel™ Conical Connection, Nobel Biocare AB
K140878, Straumann® Bone Level Tapered Implants, Straumann USA, LLC
K210499, Alpha Dent Implants Dental Implants System, Alpha Dent Implants GmbH

INDICATIONS FOR USE STATEMENT

DESS® dental implants are indicated for surgical placement in the upper or lower jaw in edentulous or partially edentulous patients to restore patient esthetics and chewing function. They are designed to support single or multi-unit restorations in splinted or non-splinted applications, as well as to retain overdentures. DESS® dental implants may be used for immediate or early implantation following extraction or loss of natural teeth and may be used for immediate or delayed loading techniques. Implants may be loaded immediately when good primary stability is achieved and occlusal loading is appropriate.

DESS® NEO GM Dental Implants are compatible with DESS® Dental Smart Solutions abutments having the identical NEO GM connection manufactured by Terrats Medical SL.

DESS® NEO GM Dental Implants with a diameter of 3.5 mm are indicated for use in reduced interdental spaces, where there is not enough alveolar bone for a larger diameter implant. The use of 3.5 mm implants is intended only for rehabilitation of the anterior region of the mouth.

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® Pre-Milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture.

Compatible Implant Systems for DESSLoc Abutments

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform Name
Astra Tech EV (Internal Taper)	3.6	3.6
	4.2	4.2
	4.8	4.8
BioHorizons (Internal)	3.8, 4.2, 4.6	3.5
	4.6, 5.2, 5.8	4.5
MIS Seven MIS M4 (Internal Hex)	3.75 ,4.2	SP (3.5)
	5.0, 6.0	WP (4.5)
NobelActive®, NobelReplace Conical NobelParallel Conical (Conical connection)	3.5, 3.75	NP (3.5)
	4.3, 5.0	RP (3.9)
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC
	4.1, 4.8	RC

Compatible Implant Systems for Pre-Milled Blank Abutments

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform Name
Implant Active Konus Implant Classic Konus Implant Active Bio (Internal Taper)	3.3, 3.75, 4.2, 5.0, 6.0	2.8

SUBJECT DEVICE DESCRIPTION

This submission includes dental implants that are compatible with DESS® Dental Smart Solutions abutments having the identical NEO GM connection manufactured by the sponsor of this submission, Terrats Medical SL, and cleared under K212628, K222288, K233316, K240208, and K242340. No claims of compatibility between the subject device implants and abutments from any OEM other than DESS® Dental Smart Solutions will be made. This submission also includes DESSLoc abutments that are compatible with eight (8) dental implant lines from five (5) OEM manufacturers. Also included in this submission is one (1) Pre-Milled Blank abutment that is compatible with three (3) implant lines manufactured by Alpha Dent Implants GmbH.

This submission includes one implant line, the Dental Implant NEO GM, a series of self-tapping, threaded, root-form dental implants to be placed at bone level. The subject device implants are provided in body diameters of 3.55 mm, 3.75 mm, 4.0 mm, 4.3 mm, 5.0 mm, 6.0 mm, and 7.0 mm. The subject device implant body diameters will be labeled as 3.5 mm, 3.75 mm, 4.0 mm, 4.3 mm, 5.0 mm, 6.0 mm, and 7.0 mm. Implant with body diameters ranging from 3.55 mm to 5.0 mm are provided in overall lengths of 7.9 mm, 9.9 mm, 11.4 mm, 12.9 mm, 15.9 mm, and 17.9 mm. Implants with body diameters 6.0 mm and 7.0 mm are provided in overall lengths of 7.9 mm, 9.9 mm, and 11.4 mm. The subject device implant lengths will be labeled as 8 mm, 10 mm, 11.5 mm, 13 mm, 16 mm, and 18 mm. All subject device implants, regardless of body diameter, have an internal Morse taper connection with a 16° included angle and 2.99 mm diameter opening at the top of the implant. This NEO GM connection is identical to the connection for abutments cleared previously in K242340.

The subject device dental implants are summarized in the following table.

Subject Device NEO GM Implants

Implant Body Ø*, mm	Implant Lengths*, mm					
	8 (7.9)	10 (9.9)	11.5 (11.4)	13 (12.9)	16 (15.9)	18 (17.9)
3.5 (3.55)	x	x	x	x	x	x
3.75	x	x	x	x	x	x
4.0	x	x	x	x	x	x
4.3	x	x	x	x	x	x
5.0	x	x	x	x	x	x
6.0	x	x	x			
7.0	x	x	x			

** labeled implant body diameter and lengths; if different, actual dimensions in parentheses*

All subject device implants are made of unalloyed titanium conforming ASTM F67 and ISO 5832-2. The entire endosseous surface, except for a small coronal bevel, features a grit blasted and double acid etched (SLA) surface, which is identical to the surface treatment for DESS® implants that were cleared in K212538.

This submission also includes DESSLoc Abutments designed for overdenture retention. The subject device DESSLoc Abutments are straight, non-engaging abutments that attach directly to the implant and are compatible with eight (8) dental implant lines from five (5) OEM manufacturers. A summary of the subject device DESSLoc Abutments, with a

list of the previously cleared submissions that included proof of the abutment compatibility with the OEM implant lines, is provided in the following table.

Subject Device DESSLoc Abutments

Compatible Implant Lines (Connection)	Implant Body Diameter, mm	Implant Platform Name	Terrats Medical 510(k) Containing Reverse Engineering or OEM Contractual Agreement
Astra Tech EV (Internal Taper)	3.6	3.6	K191986
	4.2	4.2	
	4.8	4.8	
BioHorizons (Internal)	3.8, 4.2, 4.6	3.5	K212628
	4.6, 5.2, 5.8	4.5	
MIS Seven MIS M4 (Internal Hex)	3.75 ,4.2	SP (3.5)	K240208
	5.0, 6.0	WP (4.5)	
NobelActive®, NobelReplace Conical NobelParallel Conical (Conical connection)	3.5, 3.75	NP (3.5)	K170588
	4.3, 5.0	RP (3.9)	
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC	K170588
	4.1, 4.8	RC	

The subject device DESSLoc Abutments are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136. The subject device DESSLoc abutments have a zirconium nitride (ZrN) coating produced by a physical vapor deposition (PVD) process. The ZrN coating is applied to increase the surface hardness and reduce wear of the abutment surface. The ZrN coating for the subject device DESSLoc Abutments is identical to the ZrN coating applied to DESSLoc Abutments cleared in K242340, K240208, K222288, K191986, and K170588.

This submission also includes one (1) Pre-Milled Blank Abutment that is compatible with three (3) implant lines manufactured by Alpha Dent Implants GmbH, including Implant Active Konus, Implant Classic Konus, and Implant Active Bio, cleared in cleared in K210499. Reverse engineering compatibility analysis of the Alpha Dent implants, abutments, and abutment screws and Terrats Medical SL abutments and abutment screws was provided in the prior Terrats Medical SL submission K243212.

The Pre-Milled Blank Abutment has a maximum (before milling) diameter of 10 mm and a solid cylindrical design and an engaging implant connection. The Pre-Milled Blank Abutment is manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F136. All patient-specific custom abutment fabrication for the Pre-Milled Blank Abutment 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 design parameters for the CAD-CAM fabrication of a custom abutment from the Pre-Milled Blank Abutment are:

Minimum wall thickness – 0.45 mm
Minimum post height for single-unit restoration – 4.0 mm
(post height measured above the gingival height of the final patient-matched design)
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
Pre-Milled Blanks are for straight abutments only

The abutment screw for use with the Pre-Milled Blank Abutment and the Alpha Dent implants was cleared previously in K243212.

All subject device implants are provided sterile, and all subject device abutments are provided non-sterile. The Pre-Milled Blank Abutment is supplied with the previously-cleared non-sterile abutment screw for attachment to the corresponding compatible implant. All subject device components are provided in single-unit packages for single-patient, single-use only.

PERFORMANCE DATA

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

- provided in this submission was a non-clinical worst-case MRI review to evaluate the subject device components in the MR environment using scientific rationale and published literature (T.O. Woods, J.G. 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 (March/April 2021): 783–795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition; the rationale addressed parameters per the FDA guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,* including magnetically induced displacement force and torque;
- referenced from K212538 was gamma irradiation sterilization validation (for the subject device implants) to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VD_{max}^{25}, according to ISO 11137-1 and ISO 11137-2; analysis showed that the subject device implants do not create a new worst case for gamma sterilization;
- provided in this submission was bacterial endotoxin testing (*Limulus* amebocyte lysate, LAL) according to ANSI/AAMI ST72 to demonstrate sterile product met a limit of < 20 EU/device;
- referenced from K212538 was sterile barrier shelf life for the subject device implants; referenced from K240208 was moist heat sterilization for subject device abutments 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 device abutments do not create a new worst case for moist heat sterilization;
- referenced from K212538 and K240208 was biocompatibility of the subject device components;
- referenced was compatibility information demonstrating that the subject devices (implants and abutments) are compatible with previously cleared dental implants and abutments from the sponsor Terrats Medical SL (K212628, K222288, K233316, K240208, and K242340) and other OEM implant manufacturers (K191986, K212628, K240208, and K170588, and K243212); and
- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device implants with previously cleared NEO GM abutments with angulation, including Multi-Unit Abutments (up to 30° of angulation cleared in K222288, K233316, and K242340), and Cement-retained Abutments (up to 17° of angulation cleared in K242340);

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

Intended Use and Indications for Use Statement

The subject device is substantially equivalent in intended use to the primary predicate device K212538 and the reference device K242340. All are intended to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible.

The IFUS for the subject device differs slightly from that of the primary predicate device K212538. The subject device IFUS does not include language in the IFUS of K212538 regarding implant body diameters of 3.0 mm to 3.3 mm. This difference does not change the intended use, does not raise different questions of safety or effectiveness, and does not impact substantial equivalence

The subject device IFUS and the IFUS for K242340 both contain identical language regarding the use of abutments and the requirement to send Pre-Milled Blank abutments to a Terrats Medical validated milling center for manufacture. The IFUS for the subject device differs slightly from that of the reference device K242340 in terms of the lists of the specific OEM implant compatibilities. These differences do not change the intended use, do not raise different questions of safety or effectiveness, and do not impact substantial equivalence.

Subject Device Implants

The subject device dental implants have a design similar to the implants cleared in the primary predicate device K212538. The subject device implants and the implants cleared in K212538 are manufactured from the identical material, have the identical endosseous surface treatment, and are sterilized by the same method. The range of the subject device implant body diameters (range, 3.55 mm to 7 mm) is substantially equivalent to those of the primary predicate device K212538 (range, 3 mm to 5.5 mm) and the reference device K143353 (range, 3 mm to 7 mm). The subject device implant body lengths (range, 7.9 mm to 17.9 mm) are substantially equivalent to those of the primary predicate device K212538 (range, 7 mm to 18 mm).

The subject device implants and the primary predicate device implants are manufactured from unalloyed titanium conforming to ASTM F67 and ISO 5832-2, and have the identical grit blasted and double acid etched (SLA) surface treatment applied to the endosseous surface.

The subject device implants are packaged in a vial and cap made from titanium alloy (Ti-6Al-4V) conforming to ASTM F136 and ISO 5832-3. The vial is then packaged in a polyethylene terephthalate glycol (PETG) blister pack heat sealed with a Tyvek® lid. The subject device implants are terminally sterilized by gamma irradiation. The subject device packaging and sterilization is the same as that of the primary predicate device K212538.

Subject Device Abutments

The subject device abutments and the abutments cleared in reference device K242340 have similar designs, are manufactured from the same material, and are provided non-sterile to be end-user sterilized by the same method (moist heat). Additionally, subject device abutments and the abutments cleared in reference device K242340 have the identical implant-abutment connection (NEO GM).

The subject device abutments are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 and ISO 5832-3, identical to the material used to manufacture the abutments cleared in the reference devices K242340 and K212628.

The subject device DESSLoc Abutments have the same straight design (no angulation) and a similar gingival height (5 mm or 6 mm) as the DESSLoc Abutments cleared in the reference device K242340 and the reference device K212628 (gingival height range up to 6.5 mm). The subject device DESSLoc abutments are provided with a zirconium nitride (ZrN) coating which is used to increase the surface hardness and reduce wear of the abutment surface. The ZrN coating applied to the surface of the subject device DESSLoc abutments is identical to that used on DESSLoc abutments cleared in reference device K242340.

The design parameters for the subject device Pre-Milled Blank Abutment are identical to those for the Pre-Milled Blank Abutments cleared in K242340 except for the angulation; the subject device Pre-Milled Blank Abutment are straight only with no angulation.

All subject device abutments are provided non-sterile, and the previously validated moist heat cycle, referenced from the reference device K242340, is applicable to the non-sterile subject devices.

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 identical materials. The subject device, the primary predicate, and the additional predicate devices encompass the same range of physical dimensions, are packaged in similar materials, and are sterilized using similar methods. 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 device and reference devices listed above. 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 of Substantial Equivalence*.

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	K251280 **DESS® Dental Implants** **Terrats Medical SL**	**K212538** **DESS® Dental Implants** **Terrats Medical SL**	**K242340** **DESS Dental Smart Solutions** **Terrats Medical SL**	**K143353** **Hahn Tapered Implant System** **Prismatik Dentalcraft, Inc.**
Indications for Use Statement	DESS® dental implants are indicated for surgical placement in the upper or lower jaw in edentulous or partially edentulous patients to restore patient esthetics and chewing function. They are designed to support single or multi-unit restorations in splinted or non-splinted applications, as well as to retain overdentures. DESS® dental implants may be used for immediate or early implantation following extraction or loss of natural teeth and may be used for immediate or delayed loading techniques. Implants may be loaded immediately when good primary stability is achieved and occlusal loading is appropriate. DESS® NEO GM Dental Implants are compatible with DESS® Dental Smart Solutions abutments having the identical NEO GM connection manufactured by Terrats Medical SL. DESS® NEO GM Dental Implants with a diameter of 3.5 mm are indicated for use in reduced interdental spaces, where there is not enough alveolar bone for a larger diameter implant. The use of 3.5 mm implants is intended only for rehabilitation of the anterior region of the mouth. 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® Pre-Milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture. Compatible Implant Systems *All compatible implant systems are listed on page 2 of this 510(k) Summary.*	DESS® dental implants are indicated for surgical placement in the upper or lower jaw in edentulous or partially edentulous patients to restore patient esthetics and chewing function. They are designed to support single or multi-unit restorations in splinted or non-splinted applications, as well as to retain overdentures. DESS® dental implants may be used for immediate or early implantation following extraction or loss of natural teeth and may be used for immediate or delayed loading techniques. Implants may be loaded immediately when good primary stability is achieved and occlusal loading is appropriate. Implants of diameter 3.0 mm, 3.3 mm and 3.5 mm are indicated for use in reduced interdental spaces, where there is not enough alveolar bone for a larger diameter implant. The use of 3.0 mm, 3.3 mm and 3.5 mm diameter implants is intended only for rehabilitation of the anterior region of the mouth.	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 list of OEM compatible implants is provided in the Indications for Use Statement of K242340.*	Hahn Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.
Product code	DZE, NHA	DZE	NHA	DZE
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla			
Reason for Predicate Device /Reference Device	Not applicable	Implant design, implant material, implant sterilization	Abutment designs, abutment material, abutment sterilization	Implant Diameter size

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Subject Device Implants				
Implant Design	Root-form, threaded	Root-form, threaded		Root-form, threaded
Placement	Bone-level	Bone-level		*Not stated in 510(k) Summary*
Implant diameter, mm	3.55, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0 [labeled as 3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0]	3.0, 3.3, 3.5, 4.1, 4.3, 4.8, 5.0, 5.5		3.0, 3.5, 4.3, 5.0, and 7.0
Implant length, mm	7.9, 9.9, 11.4, 12.9, 15.9, 17.9 [labeled as 8, 10, 11.5, 13, 16, 18]	7, 8, 8.5, 10, 11.5, 12, 13, 14, 15, 16, 18		8, 10, 11.5, 13, and 16
Abutment/Implant platform diameter, mm	NEO GM	2.5, 2.75, 3.0, 3.3, 4.4		*Not stated in 510(k) Summary*
Connection type	Morse taper (NEO GM)	Internal conical with hex (Active) Internal conical with anti-rotation (Bone Level)		Internal Hex
Implant Material	Unalloyed Titanium (ASTM F67)	Titanium Grade 4		Titanium Alloy, Grade 23
Endosseous surface	SLA	SLA		Blasted with Hydroxyl Apatite and acid etched
Subject Device Abutments				
Abutment Designs	DESSLoc Abutments Pre-Milled Blank Abutments		Various designs, including DESSLoc Abutments Pre-Milled Blank Abutments	
Prothesis Attachment	Cement-retained Screw-retained		Cement-retained Screw-retained	
Restoration	Single-unit Multi-unit		Single-unit Multi-unit	
Gingival Height	DESSLoc: 5 mm, 6 mm Pre milled abutment: 6 mm (maximum) 0.5 mm (minimum)		DESSLoc: 0.8 mm to 5.5 mm Pre milled abutment: 6 mm (maximum) 0.5 mm (minimum)	
Prosthetic Platform diameter	DESSLoc: not applicable Pre-Milled Blank: depends on clinically available interproximal space		DESSLoc: not applicable Pre-Milled Blank: depends on clinically available interproximal space	
Prosthetic post height (length above gingival height)	DESSLoc: not applicable Pre-Milled Blank: 4 mm (minimum for single-unit restoration)		DESSLoc: not applicable Pre-Milled Blank: 4 mm (minimum for single-unit restoration)	
Angulation in Final Abutment	DESSLoc: straight, 0° Pre milled abutment: straight, 0°		DESSLoc: straight, 0° Pre milled abutment: up to 30°	
Materials				
Abutment Material	Ti-6Al-4V (ASTM F136)		Ti-6Al-4V (ASTM F136) Co-Cr-Mo (ASTM F1537)	

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Abutment Surface	DESSLoc: Zirconium nitride (ZrN) Pre-Milled Blank: as machined		DESSLoc: Zirconium nitride (ZrN) Pre-Milled Blank: as machined	
How Provided				
Sterilization Implants	Sterile by gamma irradiation	Sterile by gamma irradiation		
Sterilization Abutments	Non-sterile		Sterile by gamma irradiation, and Non-sterile	
Usage All Components	Single patient, single use	Single patient, single use	Single patient, single use	