November 5, 2024

Terrats Medical SL
% Rebecca Kattan
Regulatory Specialist
PaxMed International, LLC
12264 El Camino Real
Suite 400
San Diego, California 92130

Re: K242340
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: August 6, 2024
Received: August 7, 2024

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)*

K242340

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 and 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**
Neodent (Morse taper GM)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM

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
K242340
Terrats Medical SL
DESS Dental Smart Solutions

November 5, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda, 75-99 Barberà del Vallès 08210 Barcelona, Spain
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Representative/Consultant	Rebecca E. Kattan, PhD 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 rkattan@paxmed.com 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

K240208, DESS Dental Smart Solutions, Terrats Medical SL
K222288, DESS Dental Smart Solutions, Terrats Medical SL
K170588, DESS Dental Smart Solutions, Terrats Medical SL
K212628, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices for OEM implant body clearances
K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
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.

The primary predicate device is K240208.
The reference device K212628 is for documentation of the compatibility of the subject device abutments with the corresponding Neodent GM 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
Neodent (Morse taper GM)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM

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 compatible with the Neodent GM implant line.

The subject device abutment designs include Healing Abutments, Temporary Abutments, Ti Base Abutments, AURUM Base Abutments, C-Base Abutments, Multi-Unit Abutments (straight and angled), Cement-retained Abutments (straight and angled), Pre-Milled Blank Abutments, DESSLoc Abutments (Locator-type abutments), and abutment screws.

Subject Device Designs

Healing Abutments are provided in gingival heights from 0.8 mm to 5.5 mm to aid in contouring the gingiva during healing. Healing Abutments are made of titanium alloy (Ti-6Al-4V).

Temporary Abutments are provided for 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 from 0.8 mm to 3.5 mm and are made of titanium alloy (Ti-6Al-4V), and with a prosthetic platform diameter of 3.5 mm or 4.5 mm.

Ti Base Abutments are provided in engaging and non-engaging designs for custom abutment fabrication of a CAD-CAM zirconia superstructure on which a crown may be placed.They also may support a ceramic hybrid abutment in which the crown is included in the design of the zirconia abutment ceramic superstructure.. 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 or hybrid abutment crown composed of zirconia. The cement recommended for bonding of superstructures is Multi-Link cement by Ivoclar Vivadent (K130436). Ti Base Abutments are manufactured from titanium alloy (Ti 6Al 4V) with the SelectGrip® surface.

Ti Base Abutments also may support a ceramic hybrid abutment in which the crown is included in the design of the zirconia abutment ceramic superstructure. When used for a direct crown, Ti Base abutments may be used with POM burn out sleeve, an exempt laboratory component not a subject of this submission, that is available for laboratory fabrication of the prosthesis. Ti Bases are not intended for angulation correction when used with a POM burn-out sleeve.

The design parameters for the CAD-CAM zirconia superstructure to be used on Ti Base Abutments are:
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 – for Ti Base with gingival height 0.8 mm or 2.5 mm – 30°
for Ti Base with gingival height 3.5 mm or 4.5 mm – 0°

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

All patient-specific custom abutment fabrication for Ti Base Abutments, AURUM Base Abutments, and C-Base Abutments (described below) is by prescription on the order of the clinician. All zirconia superstructures for use with the subject device Ti Base, AURUM Base, and C-Base Abutments will be made at a Terrats Medical validated milling center under FDA quality system regulations, and the zirconia material will conform to ISO 13356.

AURUM Base Abutments are provided in engaging and non-engaging designs. 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 Abutment 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 of 4.0 mm, 4.5 mm, and 5.5 mm, with gingival heights (in the base) of 0.8 mm, 1.5 mm, or 2.5 mm. When used for a single-unit restoration the AURUM Base is to be used with a superstructure to create a minimum post height of 4.0 mm.

AURUM Base Abutments are provided in two (2) designs, each for engaging and non-engaging connections. One design has a conical taper below the prosthetic platform that engages the compatible Neodent GM implant; this is the same design as cleared in K212628. The second design has a flat surface below the prosthetic platform that seats directly on the top of the compatible Neodent GM implant.

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 Base Abutments cleared in K240208.

The design parameters for the CAD-CAM zirconia superstructure to be used on AURUM Base Abutments are:
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
Maximum angulation – 30°

C-Base Abutments are provided in engaging and non-engaging designs. C-Base Abutments are two-piece abutments designed to support a custom CAD-CAM zirconia superstructure on which a single-unit or multi-unit restoration may be placed. The ceramic superstructure produced through CAD-CAM is the second part of the two-piece abutment. The C-Base Abutment also may support a ceramic hybrid abutment in which the crown is included in the design of the zirconia abutment ceramic superstructure.

The C-Base Abutment prosthetic post is 4.68 mm, and the gingival height is 0.8 mm. All patient-specific custom abutment fabrication is by prescription on the order of the clinician. C-Base Abutments are made of titanium alloy (Ti-6Al-4V) with anodization and a SelectGrip® surface.

C-Base Abutments also may support a ceramic hybrid abutment in which the crown is included in the design of the zirconia abutment ceramic superstructure. When used for a direct crown, C-Base abutments may be used with POM

burn out sleeve an exempt laboratory component not a subject of this submission, that is available for laboratory fabrication of the prosthesis. C-Bases are not intended for angulation correction when used with a POM burn-out sleeve.

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

Minimum wall thickness – 0.4 mm
Minimum post height (length above the abutment collar/gingival height) – 4.7 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
Maximum angulation – 30°

Multi-Unit Abutments: Straight and Angled 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 of the subject Multi-Unit Abutments are similar to the designs of Multi-Unit Abutments cleared in K240208 and K222288. All Multi-Unit Abutments are manufactured from titanium alloy (Ti-6Al-4V).

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 only in an 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 3.5 mm. The Multi-Unit Abutments angled 30° are provided with a prosthetic platform diameter of 4.8 mm, and with a gingival height of 3.5 mm.

Cement-retained Straight and Angled (17°) Abutments are designed for single-unit and multiple-unit cement-retained restorations and have a SelectGrip® surface to aid in bonding retention. The Cement-retained Straight and Angled Abutments are made of titanium alloy (Ti-6Al-4V).

Pre-Milled Blank Abutments are designed for custom abutment fabrication by a CAD-CAM process. All patient-specific custom abutment fabrication is by prescription on the order of the clinician. 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 screw-channel. The Pre-Milled Blank Abutments are manufactured from titanium alloy (Ti 6Al-4V).

The design parameters for the Pre-Milled Blank Abutments are:

Minimum wall thickness – 0.45 mm
Minimum post height (length above the abutment collar/gingival height) – 4.0 mm
Minimum gingival height – 0.5 mm
Maximum gingival height – 6.0 mm
Maximum Angulation – 30°

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.

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 two (2) 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 K240208, K222288, and K170588. Screws are made of titanium alloy (Ti-6Al-4V).

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. The reverse engineering analysis of the Neodent GM implant bodies, abutments, and abutment screws was provided in the prior Terrats Medical submission K212628.

Materials

The subject device abutments are manufactured from Ti-6Al-4V alloy conforming to ASTM F136. All zirconia superstructures for use with the subject device Ti Base, AURUM Base, and C-Base Abutments will conform to ISO 13356. 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 K240208. Ti Base Abutments, AURUM Base Abutments, and C-Base Abutments have a SelectGrip® surface to aid in bonding retention that is identical to that used on abutments cleared in K240208.

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 October 2023) including magnetically induced displacement force and torque;
- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device abutments with angulation, including Ti Base Abutments, AURUM Base Abutments, C-Base Abutments, Multi-Unit Abutments, and Cement-retained Abutments, and Pre-Milled Blank Abutments compatible with the Neodent GM implant line;
- referenced from K240208, K233316, and K222288 was biocompatibility of the subject device components;
- referenced from K240208 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 K240208 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; analysis showed that the subject devices do not create a new worst case for gamma sterilization; 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; and
- referenced from K212628 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 Neodent GM implant line.

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 K240208, and the reference devices, K222288 and K170588. 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 K240208, K222288, and K170588.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 primary predicate device K240208 and the reference devices, K222288 and K170588, are in support of substantial equivalence of the subject device designs, material, manufacturing, and biocompatibility.
All subject device abutments and screws are similar to or identical in design, materials, and technological characteristics to corresponding abutments of the primary predicate device K240208 and the reference devices K222288 and K170588. The subject submission, K240208, and K222288 all include abutments manufactured from Ti-6Al-4V alloy conforming to ASTM F136. The subject abutments are anodized by a process that is identical to that used on abutments cleared in K240208. Subject Ti Base Abutments, AURUM Base Abutments, and C-Base Abutments have a SelectGrip® surface to aid in bonding retention that is identical to the surface used on abutments cleared in K240208. All zirconia superstructures for use with the subject device Ti Base Abutments, AURUM Base Abutments, and C-Base abutments is the same zirconia material used for components cleared in K240208. The cement recommended for bonding of superstructures is Multi-Link cement by Ivoclar Vivadent (K130436). The subject Multi-Unit Abutments and DESSloc Abutments are available with and without a zirconium nitride (ZrN) coating that is identical to the ZrN coating on abutments cleared in K222288. The subject abutments screws are manufactured from Ti-6Al-4V alloy.

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 K240208, K222288, and K170588.

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 K240208. For the subject devices provided non-sterile, the previously validated moist heat cycle, referenced from the primary predicate K240208 is applicable to the non-sterile subject devices.

The risks associated with use of the subject device abutments with angulation (Ti Base Abutments, AURUM Base Abutments, C-Base Abutments, Multi-Unit Abutments, Cement-Retained Abutments, and Pre-Milled Blank Abutments) in combination with the compatible implants are mitigated by the mechanical testing provided in 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 of Substantial Equivalence.*

Table of Substantial Equivalence

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	DESS Dental Smart Solutions Terrats Medical SL	K240208 DESS Dental Smart Solutions Terrats Medical SL	K222288 DESS Dental Smart Solutions Terrats Medical SL	K170588 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. 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 510(k) Summary for K240208.*	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 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 K170588.*
Designs	Healing Abutments	Healing Abutments	Healing Abutments	Healing Abutment
	Temporary Abutments	Temporary Abutments	Temporary Abutments	Temporary Abutments
	Ti Base Abutments	Ti Base Abutments	Ti Base Abutments	Ti Base Abutments
	AURUM Base Abutments	AURUM Base Abutments		
	C-Base Abutments		C-Base Abutments	
	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°	
	Cement-retained Straight Abutments			Straight Abutment
	Cement-retained Angled 17° Abutments	Pre-Milled Blank Abutments	Pre-Milled Blank Abutments	Pre-Milled Blank Abutments
	Pre-Milled Blank Abutments			
	DESSLoc Abutments	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

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	DESS Dental Smart Solutions Terrats Medical SL	K240208 DESS Dental Smart Solutions Terrats Medical SL	K222288 DESS Dental Smart Solutions Terrats Medical SL	K170588 DESS Dental Smart Solutions Terrats Medical SL
Abutment/Implant Platform Ø, mm	3.5- 7.0	3.0 – 7.5	2.52 – 6.5	3.4-5.7
Prosthetic Platform Ø, mm	3.3- 6.5 (Neodent GM)	4.5 – 6.8	4.5 – 6.5	4.5-5.9
Superstructure Angle	angle up to 30°	angle up to 30°	angle up to 30°	Straight (0°) only
Materials				
Abutment Material- Metallic Components	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V (ASTM F136)	Ti-6Al-4V alloy (ASTM F136)	Ti-6Al-4V alloy (ASTM F136)
Abutment Surface	Anodization SelectGrip® surface Zirconium nitride (ZrN)	Anodization SelectGrip® surface	Anodization SelectGrip® surface Zirconium nitride (ZrN)	SelectGrip® surface
Abutment Material- Ceramic Components	Zirconia (Y-TZP) (ISO 13356)	Zirconia (Y-TZP) (ISO 13356)	Zirconia (Y-TZP) (ISO 13356)	Zirconia (Y-TZP) (ISO 13356)
Superstructure Cement	Multi-Link cement, Ivoclar Vivadent, K130436	Multi-Link cement, Ivoclar Vivadent, K130436	Multi-Link cement, Ivoclar Vivadent, K130436	Multi-Link cement, Ivoclar Vivadent, K130436
Screw Material	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy
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