



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

October 23, 2025

Re: K252384

Trade/Device Name: DESS® Dental Smart Solutions
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: July 30, 2025
Received: July 31, 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

Indications for Use

510(k) Number (if known)

K252384

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

Compatible Implant Systems for Pre-Milled Abutments

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
Astra Tech EV (Internal Taper)	3.0	3.0
	3.6	3.6
	4.2	4.2
BioHorizons Internal (Internal Hex)	3.0, 3.4, 3.8	3.0
	3.8, 4.2, 4.6	3.5
	4.6, 5.2, 5.8	4.5
Simply Iconic™ (Internal Conical)	3.2, 3.7, 4.2, 4.7	3.0
	4.7, 5.2, 5.7	3.4
InterActive (Internal Conical)	3.2, 3.7	3.0
	4.3, 5.0	3.4
Legacy™1 (Internal Hex)	3.7, 4.2	3.5
	4.7	4.5
Legacy™2, simplyLegacy™2, Legacy™3, simplyLegacy™3, Legacy™4 (Internal Hex)	3.2	3.0
	3.7, 4.2	3.5
	4.7, 5.2	4.5
Neodent GM (Morse taper)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
Nobel Biocare NobelActive® (Conical Connection)	3.0	3.0
	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
NobelReplace Conical Connection (Conical Connection)	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
NobelParallel Conical Connection (Conical Connection)	3.75	NP (3.5)
	4.3, 5.0	RP (3.9)
Osstem® TS Hiossen® ET (Internal Taper)	3.5	Mini
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular
Straumann Bone Level (CrossFit® Morse Taper)	3.3	NC
	4.1, 4.8	RC
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Zimmer Screw-Vent® Tapered Screw-Vent® (Internal Hex)	3.3, 3.7, 4.1	3.5
	4.7	4.5

Compatible Implant Systems for Multi-Unit Abutments

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
Biomet 3i OSSEOTITE® (External Hex)	3.25	3.4
	3.75, 4.0	4.1
InterActive (Internal Conical)	3.2, 3.7	3.0
	4.3, 5.0	3.4
Simply Iconic™ (Internal Conical)	3.2, 3.7, 4.2, 4.7	3.0
	4.7, 5.2, 5.7	3.4
Legacy™1 (Internal Hex)	3.7, 4.2	3.5
	4.7	4.5
Legacy™2, simplyLegacy™2, Legacy™3, simplyLegacy™3, Legacy™4 (Internal Hex)	3.2	3.0
	3.7, 4.2	3.5
	4.7, 5.2	4.5
Neodent GM (Morse taper)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
Nobel Biocare NobelActive® (Conical Connection)	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
NobelReplace Conical Connection (Conical Connection)	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
NobelParallel Conical Connection (Conical Connection)	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

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
K252384
Terrats Medical SL
DESS® Dental Smart Solutions
October 8, 2025

ADMINISTRATIVE INFORMATION

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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 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

Primary Predicate Device
K242340, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices
K240208, DESS Dental Smart Solutions, Terrats Medical SL
K222288, DESS Dental Smart Solutions, Terrats Medical SL
K230143, DESS Dental Smart Solutions, Terrats Medical SL
K170588, DESS Dental Smart Solutions, Terrats Medical SL
K191986, DESS Dental Smart Solutions, Terrats Medical SL
K212538, DESS Dental Implants, Terrats Medical SL
K212628, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices for OEM implant body clearances

- K111287, Astra Tech Implant System Plus, Astra Tech AB
- K101732, Astra Tech Implant System, Astra Tech AB
- K042429, BioHorizons The Prodigy System™ Endosseous Implants, BioHorizons Implant Systems, Inc.
- K071638, BioHorizons Tapered Internal Implant System, BioHorizons Implant Systems, Inc.
- K093321, BioHorizons Laser-Lok 3.0 Implant System, BioHorizons Implant Systems, Inc.
- K063341, 3i OSSEOTITE® Certain® Dental Implants, Implant Innovations, Inc.
- K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários SA
- K180536, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários S.A.
- K201225, Neodent Implant System – GM Helix Implants 7.0, JJGC Indústria e Comércio de Materiais Dentários S.A.
- K142260, NobelActive®, Nobel Biocare AB
- K073142, NobelReplace Hexagonal Implants, Nobel Biocare AB
- K173418, NobelParallel™ Conical Connection, Nobel Biocare AB
- K173961, Straumann® BLX Implant System, Institut Straumann AG
- K181703, Straumann® BLX Line Extension – Implants, SRAs and Anatomic Abutments, Institut Straumann AG
- K191256, Straumann BLX Ø3.5 mm Implants, Institut Straumann AG
- K210855, Straumann BLX Implant System, Institut Straumann AG
- K212533, BLX WB Ø5.0 (L18), Ø5.5 and Ø6.5 mm (L14 and L16) Implants, Institut Straumann AG
- K140878, Straumann® Bone Level Tapered Implants, Straumann USA, LLC
- K013227, Screw Vent Implant; Tapered Screw Vent Implant, Sulzer Dental, Inc.
- K072589, Tapered Screw-Vent Implant, 4.1mmD, Zimmer Dental, Inc.
- K061319, Spectra Dental Implant System, Implant Direct, LLC
- K192221, Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts, Implant Direct Sybron Manufacturing, LLC
- K130572, InterActive / SwishPlus 2 Implant System, Implant Direct Sybron Manufacturing LLC
- K201553, Simply Iconic™ Implants, Implant Direct Sybron Manufacturing LLC

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

Compatible Implant Systems for Pre-Milled Abutments

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
Astra Tech EV (Internal Taper)	3.0	3.0
	3.6	3.6
	4.2	4.2
BioHorizons Internal (Internal Hex)	3.0, 3.4, 3.8	3.0
	3.8, 4.2, 4.6	3.5
	4.6, 5.2, 5.8	4.5

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
Simply Iconic™ (Internal Conical)	3.2, 3.7, 4.2, 4.7	3.0
	4.7, 5.2, 5.7	3.4
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	4.3, 5.0	3.4
Legacy™1 (Internal Hex)	3.7, 4.2	3.5
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	3.7, 4.2	3.5
	4.7, 5.2	4.5
Neodent GM (Morse taper)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM
Nobel Biocare NobelActive® (Conical Connection)	3.0	3.0
	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
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	4.1, 4.8	RC
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	5.0, 5.5, 6.5	WB
Zimmer Screw-Vent® Tapered Screw-Vent® (Internal Hex)	3.3, 3.7, 4.1	3.5
	4.7	4.5

Compatible Implant Systems for Multi-Unit Abutments

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
Biomet 3i OSSEOTITE® (External Hex)	3.25	3.4
	3.75, 4.0	4.1
InterActive (Internal Conical)	3.2, 3.7	3.0
	4.3, 5.0	3.4
Simply Iconic™ (Internal Conical)	3.2, 3.7, 4.2, 4.7	3.0
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	3.7, 4.2	3.5
	4.7, 5.2	4.5
Neodent GM	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
(Morse taper)		
Nobel Biocare NobelActive® (Conical Connection)	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
NobelReplace Conical Connection (Conical Connection)	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
NobelParallel Conical Connection (Conical Connection)	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

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add abutments to the DESS Dental Smart Solutions system, which includes abutments cleared previously in K242340 and K240208. The subject device abutment designs include Pre-Milled Blank Abutments, Multi-Unit Abutments (straight and angled), and abutment screws.

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 a solid cylindrical design with an engaging or non-engaging implant connection. They are available in versions with a straight screw channel and with an angled screw channel for esthetic considerations. The Pre-Milled Blank Abutments are manufactured from titanium alloy (Ti 6Al-4V).

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 cementable post height for single-unit restoration – 4.0 mm

(minimum cementable post height for single-unit restoration is defined as the height above the restorative margin)

Minimum gingival height – 0.5 mm

Maximum gingival height – 6.0 mm

Pre-Milled Blanks are for straight abutments only

Multi-Unit Abutments: Straight and Angled are designed for attachment of multi-unit screw-retained restorations and are provided in three (3) designs, straight (0°), angled 17°, and angled 30°. The designs of the subject Multi-Unit Abutments are similar to the designs of Multi-Unit Abutments cleared in K242340 and K240208. All Multi-Unit Abutments are manufactured from titanium alloy (Ti-6Al-4V).

The subject device straight Multi-Unit Abutments have a non-engaging, threaded design that attaches directly to the implant. The subject device straight (0°) Multi-Unit Abutments are included in this submission are similar in design to straight Multi-Unit Abutments cleared in K242340, K230143, and K222288. Subject device straight Multi-Unit Abutments are provided with a prosthetic platform diameter of 4.8 mm, and with a gingival height ranging from 1 mm to 5.5 mm.

The subject device angled Multi-Unit Abutments are provided only in an engaging design that requires an abutment screw. The subject device Multi-Unit Abutments angled 17° and 30° are provided with a prosthetic platform diameter of 4.8 mm, and with a gingival height ranging from 2.5 to 4.5 mm.

Select straight and angled Multi-Unit Abutments have an added coating of zirconium nitride (ZrN). This coating is identical to the ZrN coating used on abutments with ZrN cleared in K242340.

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 seventeen (17) 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 K242340 and K240208. Screws are made of titanium alloy (Ti-6Al-4V). Select subject device screws are available with DLC (Diamond-like Carbon) coating and are identical to that used on screws cleared in K240208.

OEM Implant Compatibility

To ensure that the subject abutments and screws are designed to fit the corresponding OEM implants, the dimensions and tolerances of subject abutments and screws have been established by reverse engineering dimensional analysis of OEM implant bodies, OEM abutments, and OEM abutment screws or by a cooperative arrangement with the OEM implant manufacturer. The subject device abutments have the same OEM implant compatibilities as the components cleared in K170588, K191986, K212628, and K230143, except for the 3.2 mm diameter implants of the Legacy™2, simplyLegacy™2, Legacy™3, simplyLegacy™3 and Legacy™4 implant lines from Implant Direct Sybron Manufacturing, LLC, for which a new Letter of Authorization has been provided.

Materials

The subject device abutments and the subject device screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 and ISO 5832-3. Select abutments are colored by an anodization process that is identical to that used on abutments cleared in K242340. Select subject device straight and angled Multi-Unit abutments have a Zirconium Nitride (ZrN) coating used to increase the surface hardness and reduce wear on the surface. This coating is identical to the ZrN coating used on abutments with ZrN cleared in K242340. Select subject device screws are available with DLC (Diamond-like Carbon) coating and is identical to that used on screws 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 and abutment screws) 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;
- 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 abutments do not create a new worst case for gamma sterilization;
- provided in this submission was bacterial endotoxin testing (*Limulus* ameocyte lysate, LAL) according to ANSI/AAMI ST72 to demonstrate sterile product met a limit of < 20 EU/device;
- referenced from K170588 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 K242340 and K240208 was biocompatibility of the subject device components;
- referenced from K170588, K191986, K212628, and K230143 was compatibility of the subject abutments and the OEM implants listed in the Indications for Use Statement;

- provided in this submission was a new Letter of Authorization from the OEM implant manufacturer for 3.2 mm diameter implants from Implant Direct Sybron Manufacturing, LLC; and
- provided in this submission was mechanical testing conducted according to ISO 14801 to support the performance of the subject device abutments in conjunction with the compatible OEM implants.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in intended use to the primary predicate device K242340 and the reference device K240208. All are intended to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible.

The subject device IFUS and the IFUS for the primary predicate device K242340 both contain identical language regarding the use of abutments and the requirement to send Pre-Milled Blank abutments to the Terrats Medical validated milling center for manufacture. The IFUS for the subject device differs slightly from that of the primary predicate device K242340 and reference device K240208 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.

The primary predicate device K242340 and the reference device K240208, are in support of substantial equivalence of the subject device designs, material, manufacturing, and biocompatibility.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, and are made of identical materials. The subject device, the primary predicate, and the reference 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 device 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
	DESS Dental Smart Solutions Terrats Medical SL	K242340 DESS Dental Smart Solutions Terrats Medical SL	K240208 DESS Dental Smart Solutions Terrats Medical SL
Product Code	NHA	NHA	NHA
Reason for Predicate Device /Reference Device	n/a	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
Indications for Use Statement	<p>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.</p> <p>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.</p> <p><i>The complete Indications for Use Statement with OEM implant compatibilities is provided in this 510(k) Summary.</i></p>	<p>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.</p> <p>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.</p> <p><i>The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K242340.</i></p>	<p>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.</p> <p>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.</p> <p><i>The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K240208.</i></p>
Designs	Pre-Milled Blank Abutments	Pre-Milled Blank Abutments	Pre-Milled Blank Abutments
	Multi-Unit Abutments, Straight	Multi-Unit Abutments, Straight	Multi-Unit Abutments, Straight
	Multi-Unit Abutments, Angled 17° and 30°	Multi-Unit Abutments, Angled 17° and 30°	Multi-Unit Abutments, Angled 17° and 30°
	Abutment Screws	Abutment Screws	Abutment Screws
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
Prosthetic Platform Ø, mm	Pre-Milled: 10 (max) and 14 (max) Multi-Unit: 4.8	Pre-Milled: 10 (max) and 14 (max) Multi-Unit: 4.8	Pre-Milled: 10 (max) and 14 (max) Multi-Unit: 4.8

Comparison	Subject Device	Primary Predicate Device	Reference Device
	DESS Dental Smart Solutions Terrats Medical SL	K242340 DESS Dental Smart Solutions Terrats Medical SL	K240208 DESS Dental Smart Solutions Terrats Medical SL
Abutment Angle	Pre-Milled: Straight (0°) Multi-Unit: 0°, 17°, 30°	Pre-Milled: 30° Multi-Unit: 0°, 17°, 30°	Pre-Milled: Straight (0°) Multi-Unit: 0°, 17°, 30°
Gingival Height, mm	Pre-Milled Blank: 6 (max) Multi-Unit: 1.0 - 5.5	Pre-Milled Blank: 6 (max) Multi-Unit: 0.8 - 5.5	Pre-Milled Blank: 6 (max) Multi-Unit: 0.8 - 5.5
Materials			
Abutment Material	Ti-6Al-4V alloy	Ti-6Al-4V alloy	Ti-6Al-4V alloy Co-Cr-Mo alloy
Abutment Surface	Anodization Zirconium nitride (ZrN)	Anodization SelectGrip® surface Zirconium nitride (ZrN)	Anodization SelectGrip® surface Zirconium nitride (ZrN)
Screw Material	Ti-6Al-4V alloy DLC coating	Ti-6Al-4V alloy	Ti-6Al-4V alloy DLC coating
How Provided			
Sterilization	Sterile by gamma irradiation, and Non-sterile	Sterile by gamma irradiation, and Non-sterile	Sterile by gamma irradiation, and Non-sterile
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use