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

June 9, 2026

Re: K260564
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: February 20, 2026
Received: May 6, 2026

Dear Melissa Burbage:

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

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

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

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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)*

K260564

Device Name

DESS Dental Smart Solutions

Indications for Use *(Describe)*

DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed custom abutments for use with DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture.

The PEEK Abutments are premanufactured prosthetic component directly connected to the endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.

Compatible Implant Systems

Implant Compatibility (Connection)	**Implant Body Diameter, mm**	**Implant Platform, mm**
NobelActive® NobelReplace/ NobelParallel Conical	3.0	3.0
	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
	5.5	WP (5.1)
NobelReplace® Trilobe	3.5	NP (3.5)
	4.3	RP (4.3)
	5.0	WP
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Keystone Paltop Dynamic (Internal Hex)	3.0, 3.25	NP (3.25)
PALTOP ADVANCED CLASSIC (Internal Hex)	3.25	NP (3.25)
PALTOP ADVANCED PLUS (Internal Hex)	3.0, 3.25	NP (3.25)
Keystone Paltop Dynamic Conical (Internal conical)	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)
Genesis Active (Internal conical)	3.5, 3.8, 4.5, 5.5	CC (3.5/3.8/4.5/5.5)
PALTOP Implants (Internal conical)	3.25	NP (3.25)
Keystone Prima Plus Conical (Internal conical)	3.5, 4.1, 5.0, 6.0	CC (3.5, 4.1, 5.0, 6.0)

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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510(k) Summary
Terrats Medical SL
DESS® Dental Smart Solutions
K260564

June 9, 2026

ADMINISTRATIVE INFORMATION

Manufacturer Name	Terrats Medical SL Carrer Mogoda 75-99 Barberà del Vallès 08210 Barcelona, Spain Telephone: +34 935 646 006 Fax: +34 935 647 317
Official Contact	Roger Terrats, CEO
Representative/Consultant	Melissa Burbage Enerxen Consulting, Inc. 1155 Metcalfe Street, Suite 1572 Montreal, Quebec H3B 2V6 Telephone: +1 619-480-7733 Email: melissa.burbage@enerxen.com Sergio Muñoz, Terrats Medical SL Barberà del Vallès 08210 Barcelona, Spain Telephone +34 935 646 006 Email sergio.munoz@dessdental.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	DESS Dental Smart Solutions
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
Primary Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Division	DHT1B: Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device

K170588, DESS Dental Smart Solutions, Terrats Medical SL

Reference Devices

K222269, DESS Dental Smart Solutions, Terrats Medical SL

K240208, DESS Dental Smart Solutions, Terrats Medical SL
K120954, Nobel Procera PEEK Abutments, Nobel Biocare AB

Reference Devices for OEM implant body clearances
K210117, Paltop Narrow Implant, Paltop Advanced Dental Solutions, Ltd.
K223814, Genesis Implant System, Keystone Dental, Inc.
K243983, Paltop Dental Implant System, Paltop Advance Dental Solutions, Ltd
K232740, Paltop Short Implants, Paltop Advanced Dental Solutions, Ltd
K220200, Paltop Concial Implant System, Paltop Advance Dental Solutions, Ltd
K240966, Prima Plus Conical Implant System, Keystone Dental, Inc.
K142260, NobelActive®, Nobel Biocare AB
K102436, NobelActive® 3.0, Nobel Biocare AB
K173418, NobelParallel™ Conical Connection, Nobel Biocare AB
K050705, TiUnite Implants®, Nobel Biocare AB
K050406, NOBELSPEEDY™ Implants, Nobel Biocare USA LLC
K022562, Various Brånemark System Implants–Immediate Function Indication, Nobel Biocare

INDICATIONS FOR USE STATEMENT

DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally designed custom abutments for use with DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture.

The PEEK Abutments are premanufactured prosthetic component directly connected to the endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation

Compatible Implant Systems

Implant Compatibility (Connection)	**Implant Body Diameter, mm**	**Implant Platform, mm**
NobelActive® NobelReplace/ NobelParallel Conical	3.0	3.0
	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
	5.5	WP (5.1)
NobelReplace® Trilobe	3.5	NP (3.5)
	4.3	RP (4.3)
	5.0	WP
Nobel Brånemark System®	3.3	NP
	3.75, 4.0	RP
	5.0	WP
Keystone Paltop Dynamic (Internal Hex)	3.0, 3.25	NP (3.25)
PALTOP ADVANCED CLASSIC (Internal Hex)	3.25	NP (3.25)
PALTOP ADVANCED PLUS (Internal Hex)	3.0, 3.25	NP (3.25)
Keystone Paltop Dynamic Conical (Internal conical)	3.25, 3.75, 4.2, 5.0	CC (3.25/3.75/4.2/5.0)
Genesis Active (Internal conical)	3.5, 3.8, 4.5, 5.5	CC (3.5/3.8/4.5/5.5)
PALTOP Implants (Internal conical)	3.25	NP (3.25)
Keystone Prima Plus Conical (Internal conical)	3.5, 4.1, 5.0, 6.0	CC (3.5, 4.1, 5.0, 6.0)

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components to the DESS Dental Smart Solutions system, which includes abutments previously cleared under K170588, K222269, and K240208 to include a healing abutment design using PEEK for three existing Noble connections, a temporary abutment design using PEEK for existing DESS MultiUnite abutments, and include bases and Pre-Milled Blanck for Keystone connections.

	Subject Device Components								
OEM Implant lines	Peek healing	Peek Temporary	Ti base	Aurum	C-Base	Elliptical	Premilled	MUA	Screw
NobelActive® NobelReplace Conical NobelParallel Conical	X								
NobelReplace ® Trilobe	X								
Nobel Brånemark System®	X								
Keystone Paltop (Internal Hex)						X			X
Genesis Active (Internal conical) Keystone Paltop Dynamic Conical			X	X	X	X	X	X	X
Multi unite abutments		X							

Subject Device Designs

Healing Abutments are provided in gingival heights from 3 mm to 5 mm to aid in contouring the gingiva during healing. Healing Abutments are made of PEEK.

Temporary Abutments are provided for 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 1.5 mm and are made of PEEK, and with a prosthetic platform diameter of 4.5 mm to 6.0 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 required 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.

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 5.5 mm, with gingival heights (in the base) of 1 mm.

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.

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 1 mm to 3 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 POMburn 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.

ELLIPTIBase Abutments are available in an engaging design. ELLIPTIBase 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 ELLIPTIBase Abutment also may support a ceramic hybrid abutment in which the crown is included in the design of the zirconia abutment ceramic superstructure.

Before attachment of the zirconia superstructure or crown, the ELLIPTIBase post height is 3.0 mm. When used for a single-unit restoration the ELLIPTIBase is to be used with a superstructure to create a minimum post height of 4.0 mm. ELLIPTIBase is made of titanium alloy (Ti-6Al-4V ELI) with a gold anodized surface

The design parameters for the CAD/CAM zirconia superstructures are summarized in Table 1 and Figure 1 below.

Table 1 Design Parameters for all DESS Base Abutments

Abutment Base			Zirconia Superstructure				Final Abutment	
Type	Prosthetic Platform Ø (Abutment base Ø), mm	Gingival Height[1], mm	Minimum wall thickness, mm	*Dimension B* Minimum Abutment Post Height[2] for single-unit restorations, mm	*Dimension D* Gingival height[3], Minimum/ maximum, mm	*Dimension F* Maximum Angulation	*Dimension A* Total height, Minimum/ maximum, mm	*Dimension E* Width, Minimum/ maximum, mm
Ti base	5.5	1-2	0.4	4.2	0.5 / 6.0	30°	5.7 / 20.2	Based on minimum wall thickness / 14
	5.5	3	0.4	4.2	0.5 / 6.0	0°	7.7 / 20.2	Based on minimum wall thickness / 14
Aurum Base	5.5	1	0.4	4.0	0.5 / 6.0	30°	5.5 / 18	Based on minimum wall thickness / 14
C-Base	4.3-5.5	1-2	0.4	4.7	0.5 / 6.0	30°	6.2 / 17	Based on minimum wall thickness / 14
	4.3-5.5	3	0.4	4.7	0.5 / 6.0	0°	8.2 / 17	Based on minimum wall thickness / 14
ELLIPTIBase (internal conical)	4.1	1	0.4	4.0	0.5/6.0	30°	5.5 / 18	Based on minimum wall thickness / 14
ELLIPTIBase (internal hex)	4.1	1	0.4	4.0	0.5/6.0	0°	5.5 / 18	Based on minimum wall thickness / 14

[1] Gingival collar height in the abutment base; [2] Abutment post height is the portion above the gingival height of the final patient-matched design; [3] Gingival height in the zirconia superstructure

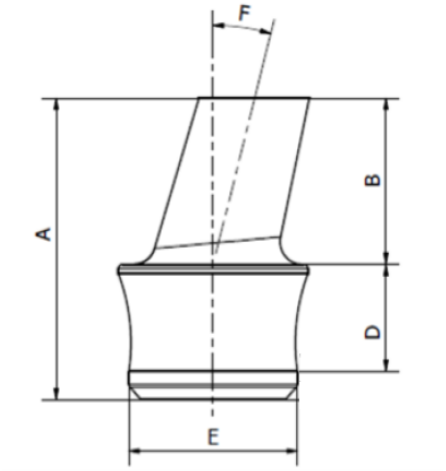

Figure 1 Design Parameters

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.

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 of 3 mm and 4 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 4 mm. The Multi-Unit Abutments angled 30° are provided with a prosthetic platform diameter of 4.8 mm, and with a gingival height of 4 mm and 5 mm.

Pre-Milled Blank Abutments are designed for custom abutment fabrication by a CAD-CAM process. All patientspecific 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 abutment 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 – 0º - intended for straight abutments only

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 eight (8) 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 K170588, K222269, and K240208. Screws are made of titanium alloy (Ti-6Al-4V).

MATERIAL COMPOSITION

The subject device healing and temporary abutments are manufactured from PEEK Classix from Invibio Ltd. This is the same material that is used in predicate K120954.

The metallic components of the subject device Ti base Abutments, C-Base Abutments, ELLIPTI Base, AURUM Base, Multi-Unit Abutments, Pre-Milled Blanks, and screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401*). There have been no changes to the material as cleared in K170588, K240208, and K222269.

The material required for zirconia superstructures on Ti Base, DESS Aurum Base and ELLIPTIBase, and C-Base is VITA YZ ST and VITA YZ XT, conforming to ISO 6872 *Dentistry – Ceramic Materials* and cleared in K180703. The cement required in labeling for bonding of superstructures is Multilink Hybrid Abutment Cement from Ivoclar Vivadent AG, cleared under K130436. There have been no changes to the material as cleared in K170588, K240208, and K222269.

PERFORMANCE DATA

Non-clinical testing data submitted to demonstrate substantial equivalence included:

- Leveraged sterilization validation according to ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* and ISO 17665-2 *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1* for the subject device composed of titanium and zirconia. Conducted validation for the PEEK subject device abutments.
- Biocompatibility testing according to ISO 10993-5 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* for PEEK subject device abutment.
- Leveraged biocompatibility testing according to ISO 10993-5 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* for subject devices composed of titanium and zirconia.
- Non-clinical worst-case MRI review to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the subject device components and material composition. 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.
- Leveraged reverse engineering analysis and contractual agreement with OEM manufacture from K170588, K222269, and K240208 of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility for OEM connections.
- Fatigue testing of OEM implant bodies with patient specific abutments made at worst-case angled conditions.

EQUIVALENCE TO MARKETED DEVICES

Table 2 Table of Substantial Equivalence

Comparison	Subject Device	Predicate Devices	Additional Predicate
	DESS Dental Smart Solutions Terrats Medical SL	K170588, K222269, K240208 DESS Dental Smart Solutions Terrats Medical SL	K120954 Nobel Procera PEEK Abutments
Product Code	NHA	NHA	NHA
Reason for predicate/reference	n/a	Indications, Abutment design, OEM Connections	PEEK Material
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	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture. The PEEK Abutments are premanufactured prosthetic component directly connected to the endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed custom abutments for use with DESS Bases or Blanks are to be sent to a Terrats Medical validated milling center for manufacture.	The Nobel Biocare PEEK Abutments are premanufactured prosthetic components directly connected to endosseous dental implants and are intended for provisional use up to 180 days as an aid in prosthetic rehabilitation.
Design Temporary, Healing		K170588	
Abutment Diameter, mm	4.5 – 6.0	3.4 – 5.7	---
Gingival Height, mm	1.5	0 – 6	---
Abutment Angulation	Straight	Straight	Straight
Abutment/Implant Interface	Internal Thread	Internal Thread	Internal Thread
OEM	Nobel Active, Nobel Replace, Nobel Branemark, DESS	Nobel Active, Nobel Replace, Nobel Branemark, DESS	---
Material	PEEK	Ti 6Al-4V ELI	PEEK
Duration of PEEK use	180 days	N/A	180 days
Design Base Abutment		K240208	
Abutment Diameter, mm	4.1 – 5.5	3.85 – 7.0	---
Gingival Height (of superstructure), mm	0.5 – 6	0.5 – 6	---
Abutment Angulation	0° – 30°	0° – 30°	---

Comparison	Subject Device	Predicate Devices	Additional Predicate
	DESS Dental Smart Solutions Terrats Medical SL	K170588, K222269, K240208 DESS Dental Smart Solutions Terrats Medical SL	K120954 Nobel Procera PEEK Abutments
Abutment/Implant Interface	Internal Thread	Internal Thread	---
OEM Connection	Keystone Internal Conical, Keystone Internal Hex	Keystone Internal Conical, Keystone Internal Hex	---
Material	Zirconia and Ti 6Al-4V ELI	Zirconia and Ti 6Al-4V ELI	---
Surface Treatment	SelectGrip or Anodization	SelectGrip or Anodization	---
Design Premilled Blank		K222269	---
Abutment Diameter, mm	4.1 – 5.5	2.9 – 5.7	---
Gingival Height, mm	0.5 – 6	0.5 – 6	---
Abutment Angulation	Straight	Straight	---
Abutment/Implant Interface	Internal Thread	Internal Thread	---
OEM Connection	Keystone Internal Conical	Keystone Internal Conical	---
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI	---
Surface Treatment	None	None	---
Design Multi Unit Abutment		K222269	---
Abutment Diameter, mm	4.8	2.9 – 5.7	---
Gingival Height, mm	1 – 5	0.5 – 6	---
Abutment Angulation	0°, 17°, 30°	0°, 17°, 30°	---
Abutment/Implant Interface	Internal Thread	Internal Thread	---
OEM Connection	Keystone Internal Conical	Keystone Internal Conical	---
Material	Ti 6Al-4V ELI	Ti 6Al-4V ELI	---
Surface Treatment	Anodization	None	---
Reprocessing			
Abutment	End user steam sterilization	End user steam sterilization	End user steam sterilization

The indications for use of the subject device healing and temporary abutments are identical to the predicate device K120954. Both are premanufactured components that are intended to directly connect to the dental implant for provisional use up to 180 days to aid in prosthetic rehabilitation.

The indications for use of the subject device Ti Base (all types) and Pre-Milled Blank abutments are identical to the predicate device K170588, K222269, and K240208. Both are intended for use with endosseous dental implants to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. Fabrication of the digitally design abutments are to occur at a DESS validated milling center.

The indications for use of the subject device Multi-Unit abutments are identical to the predicate device K170588, K222269, and K240208. Both are intended for use with endosseous dental implants to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible.

All subject device abutments are similar or identical in design, materials and technological characteristics to corresponding abutments of the primary predicate device K170588 and the additional predicate devices K222269, K240208, and K120954.

The design of the Temporary and Healing abutment is the same as predicate devices K170588 and K222269. The PEEK material is the same as additional predicate device K120954.

The design of the Base Abutments (Ti Base, AURUM, C-Base, ELLIPTIBase models) is the same as predicate devices K170588 (abutment design) and K240208 (angulation and OEM connection).

The SelectGrip® surface on the subject device Ti Base Abutments is identical to the Select Grip® surface on equivalent abutments cleared in K170588, K222269, and K240208. The gold anodized surface on the subject device AURUM Base Abutments is identical to the anodized surface on Aurum Abutments of the predicate devices K170588, K222269, and K240208.

The cement required in labeling for bonding of superstructures is Multi-Link cement from Ivoclar Vivadent, cleared under K130436. This is the same cement required in labeling for the predicate devices K170588, K222269, and K240208.

All screws are identical in design, materials, and technological characteristics to those cleared in predicate devices K170588, K222269, and K240208, except for threads and lengths that accommodate the new compatibilities. The Diamond-like carbon (DLC) coating and Anodized applied to all screws is identical to anodizing or DLC surface on screws cleared in predicate device K252384, K240208 and K222269.

The design, including angulation, of the Multi-Unit Abutment is the same as the predicate K222269 with the exception of gold anodization. The gold anodized surface on the subject device Multi-Unit Abutment is identical to the anodized surface on Aurum Abutments of the predicate devices K170588 and K222269.

The risks associated with use of angulated abutments in combination with the compatible implants are mitigated by the mechanical testing.

The subject device is provided non-sterile to the end user for the end user to sterilize prior to use, the same as the primary predicate. The sterilization validation was conducted for the PEEK abutment.

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 the same materials. The subject device, the primary predicate, and additional predicate devices encompass the same range of physical dimensions, are packaged in similar materials, and are to be sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.