April 16, 2026

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

Re: K253804
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: November 28, 2025
Received: March 19, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K253804

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.

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Implant Platform Name
Ankylos C/X	3.5, 4.5, 5.5	3.5, 4.5, 5.5
Astra Tech EV	3.6	3.6
	4.2	4.2
	4.8	4.8
	5.4	5.4
Astra Tech OsseoSpeed™	3.0	3.0
	3.5/4.0	3.5/4.0
	4.5/5.0	4.5/5.0
BioHorizons Internal	3.0, 3.4, 3.8	3.0
	3.8, 4.6	3.5
	4.6, 5.8	4.5
	5.8	5.7
Biomet 3i Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
Biomet 3i OSSEOTITE®	3.25	3.4
	3.75, 4.0	4.1
	5.0	5.0
Keystone Prima Connex	3.3, 3.5	3.5
	4.0, 4.1	4.1
	5.0	5.0
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
MIS C1	3.30	NP
	3.75, 4.20	SP
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive® NobelReplace/ NobelParallel Conical	3.5	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
Straumann® BLX	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Zimmer Screw-Vent® / Tapered Screw-Vent®	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary
Terrats Medical SL
DESS® Dental Smart Solutions
K253804

April 16, 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

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
K251547, DESS Dental Smart Solutions, Terrats Medical SL

Reference Device
K170588, DESS Dental Smart Solutions, Terrats Medical SL
K191986, DESS Dental Smart Solutions, Terrats Medical SL
K212628, DESS Dental Smart Solutions, Terrats Medical SL
K222269, DESS Dental Smart Solutions, Terrats Medical SL
K242340, DESS Dental Smart Solutions, Terrats Medical SL
K233587, LOCATOR® Angled Abutment (Various), Zest Anchors, LLC

Reference Devices for OEM implant body clearances
K140347, ANKYLOS C/X Implant System, Dentsply International Inc.
K111287, Astra Tech Implant System Plus, Astra Tech AB

K120414, OsseoSpeed™ Plus, Astra Tech AB
K101732, Astra Tech Implant System, Astra Tech AB
K042429, BioHorizons The Prodigy System™ Endosseous Implants, BioHorizons Implant Systems
K071638, BioHorizons Tapered Internal Implant System, BioHorizons Implant Systems, Inc.
K063341, 3i OSSEOTITE® Certain® Dental Implants, Implant Innovations, Inc.
K063286, OSSEOTITE Dental Implants, Implant Innovations, Inc.
K051614, PrimaConnex Internal Connection, Lifecore Biomedical (Keystone)
K072768, Restore®, Stage-1®, Renova®, PrimaSolo®, and PrimaConnex® Dental Implants, Lifecore Biomedical, Inc.
K101545, Genesis Implant System, Keystone Dental, Inc.
K172505, MIS C1 Narrow Platform Conical Connection Implant System, MIS C1 Wide Platform Conical Connection, MIS Implants Technologies Ltd
K163194, Neodent Implant System – GM Line, JJGC Indústria e Comércio de Materiais Dentários
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
K173961, Straumann® BLX Implant System, Institut Straumann AG
K130222, Straumann® Dental Implant System SLActive and Roxolid Product Families, Straumann
K011028, Screw-Vent Implant; Tapered Screw-Vent Implant, Sulzer Dental, Inc.
K112160, Tapered Screw-Vent X Implant, Zimmer Dental, Inc.

INDICATIONS FOR USE STATEMENT

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

Compatible Implant Systems

Implant System Compatibility	Implant Diameter (mm)	Implant Platform Name
Ankylos C/X	3.5, 4.5, 5.5	3.5, 4.5, 5.5
Astra Tech EV	3.6	3.6
	4.2	4.2
	4.8	4.8
	5.4	5.4
Astra Tech OsseoSpeed™	3.0	3.0
	3.5/4.0	3.5/4.0
	4.5/5.0	4.5/5.0
BioHorizons Internal	3.0, 3.4, 3.8	3.0
	3.8, 4.6	3.5
	4.6, 5.8	4.5
	5.8	5.7
Biomet 3i Certain®	3.25	3.4
	4.0	4.1
	5.0	5.0
Biomet 3i OSSEOTITE®	3.25	3.4
	3.75, 4.0	4.1
	5.0	5.0
Keystone Prima Connex	3.3, 3.5	3.5
	4.0, 4.1	4.1
	5.0	5.0
MegaGen AnyRidge	3.5, 4.0, 4.5, 5.0, 5.5	3.5
MIS C1	3.30	NP
	3.75, 4.20	SP
Neodent Grand Morse	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	Grand Morse (GM)
NobelActive® NobelReplace/ NobelParallel Conical	3.5	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
Straumann® BLX	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann® Bone Level	3.3	NC
	4.1, 4.8	RC
Zimmer Screw-Vent® / Tapered Screw-Vent®	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to expand the DESS Dental Smart Solutions to include an angled version of the DESSLoc abutment and to include straight DESSLoc abutments for the 3.0 mm implant-abutment platform diameter for BioHorizons, as well as additional gingival height options for straight DESSLoc abutments BioHorizons (Implant-Abutment Platform 3.5mm and 4.5mm), Straumann Bone Level (Implant-Abutment Platform NC (3.3mm)), and Zimmer (Implant-Abutment Platform 3.5mm and 4.5mm) connections, as outlined in the tables below.

The DESSLoc Attachment System consists of abutments and device-specific accessories (retention inserts and denture housings) for resilient attachment of prostheses to endosseous dental implants. The design of the DESSLoc abutments has been changed to provide an 18° angled abutment with various OEM connections that have been previously cleared. The abutments are made of titanium alloy and are coated with zirconium nitride (ZrN). The system uses existing retention inserts manufactured from Polynil® (polyamide 6.6) or Vestamid® Care ML GB30 (polyamide 12), and existing denture housings made of titanium alloy with a machined or anodized surface. The DESSLoc abutment is compatible with OEM implants, as listed below.

Table 1 Summary of OEM Compatibilities for Angled DESSLoc Attachment System

Compatible Implant Lines	DESS Abutment System Name	Implant-Abutment Platform Ø, mm	Implant Body Ø, mm	Gingival Height, mm
Ankylos C/X	Internal Ank	2.52	3.5, 4.5, 5.5	1, 2, 3, 4, 5
Astra Tech EV	Conic EVO	2.9	3.6	1, 2, 3, 4, 5
		3.5	4.2	1, 2, 3, 4, 5
		4.1	4.8	1, 2, 3, 4, 5
		5.4	5.4	1, 2, 3, 4, 5
Astra Tech OsseoSpeed™	Internal Hex Conic	3.5	3.5	1, 2, 3, 4, 5
		4.0	4.0	1, 2, 3, 4, 5
BioHorizons Internal	Internal Hex BH	3.5	3.8, 4.6	1, 2, 3, 4, 5
		4.5	4.6, 5.2, 5.8	1, 2, 3, 4, 5
		5.7	5.8, 7, 8	1, 3, 5
Biomet 3i Certain®	Internal Hex "Click"	3.4	3.25	1, 2, 3, 4, 5
		4.1	4.0	1, 2, 3, 4, 5
Biomet 3i OSSEOTITE®	External Hex USA	3.4	3.25	1, 2, 3, 4, 5
Keystone Prima Connex	Internal Tilobe	3.5, 3.8	3.3, 3.5, 3.8	1, 3, 5
		4.1, 4.5	4.0, 4.1, 4.5	1, 3, 5
		5.0, 5.5, 5.7, 6.0, 6.5	5.0, 5.5, 6.0, 6.5	1, 3, 5
MegaGen AnyRidge	Conic Anyr	3.5	3.5, 4.0, 4.5, 5.0, 5.5	1.5, 3, 4.5
MIS C1	MIS C1 Internal	NP (3.3)	3.3	1, 2, 3, 4, 5
		SP	3.75, 4.2	1, 2, 3, 4, 5
Neodent Grand Morse	Neo GM	Grand Morse (GM)	3.5, 3.75, 4.0, 4.3, 5.0, 6.0, 7.0	1, 2, 3, 4, 5
NobelActive®, NobelParallel Conical	Active Hex	NP (3.5)	3.5	1, 2, 3, 4, 5
		RP (4.3)	4.3, 5.0	1, 2, 3, 4, 5
NobelReplace ® Trilobe	Tri-lobe	NP (3.5)	3.5	1, 3, 5
		RP (4.3),	4.3	1, 3, 5
Nobel Brånemark System®	External Hex Universal	NP (3.5)	3.3	1, 2, 3, 4, 5
		RP (4.1)	3.75, 4.0	1, 2, 3, 4, 5
Straumann BLX	Conical BLX	RB/WB	3.5, 3.75, 4.0, 4.5, 5.0, 5.5, 6.5	1, 2, 3, 4, 5
Straumann® Bone Level	Conical BL	NC (3.3)	3.3	1, 2, 3, 4, 5
		RC (4.1)	4.1, 4.8	1, 2, 3, 4, 5
Zimmer Screw-Vent / Tapered Screw-Vent	Internal Hex USA	3.5	3.7, 4.1	1, 2, 3, 4, 5
		4.5	4.7	1, 2, 3, 4, 5
		5.7	6.0	1, 3, 5

Table 2 Summary of OEM Compatibilities for Straight DESSLoc Attachment System

Compatible Implant Lines	DESS Abutment System Name	Implant-Abutment Platform Ø, mm	Implant Body Ø, mm	Gingival Height, mm
BioHorizons Internal	Internal Hex BH	3.0	3.0, 3.4, 3.8	1, 2, 3, 4, 5, 6
		3.5	3.8, 4.6	0.5
		4.5	4.6, 5.2, 5.8	0.5
Straumann® Bone Level	Conical BL	NC (3.3)	3.3	1
Zimmer Screw-Vent / Tapered Screw-Vent	Internal Hex USA	3.5	3.7, 4.1	0.5
		4.5	4.7	0.5

MATERIAL COMPOSITION

All abutments and metal denture housing are manufactured from titanium alloy conforming to the requirements of ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*.

PERFORMANCE DATA

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

- Leveraged sterilization validation from K251547 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 abutments.
- 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 of OEM implant bodies from K170588, K191986, K212628, K222269, K242340, and K251547, OEM abutments, and OEM abutment screws to confirm compatibility for new OEM connections.
- Fatigue testing of OEM implant bodies with abutments at worst-case angled conditions.

EQUIVALENCE TO MARKETED DEVICES

Table 3 Table of Substantial Equivalence

Comparison	Subject Device	Predicate Device	Reference Device
	DESS Dental Smart Solutions Terrats Medical SL	K251547 DESS Dental Smart Solutions Terrats Medical SL	K233587 LOCATOR Angled Abutment Zest Anchors, LLC
Product Code	NHA	NHA	NHA
Reason for predicate/reference	n/a	Indications, Abutment design, OEM Connections	Angled Abutment Design
Intended Use	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function	Support of a prosthesis to restore chewing function
Indications	DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.	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.	The LOCATOR Angled Abutment is indicated for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants to restore masticatory function for the patient.
Design			
Abutment Diameter, mm	2.9 – 5.7	2.9 – 5.7	3.25 – 6.5
Gingival Height, mm	0.5 – 6	0 – 6	1 – 6
Abutment Angulation	Straight, Angled	Straight	Angled
Abutment/Implant Interface	Internal Thread	Internal Thread	Internal Thread
Restoration type	Overdenture	Overdenture	Overdenture
Divergence Allowance	18°/36°	0°	15°/30°
Prosthesis Attachment Type	Nylon Insert retained in Denture Housing	Nylon Insert retained in Denture Housing	Nylon Insert retained in Denture Housing
Material			
Abutment	Ti 6Al-4V ELI	Ti 6Al-4V ELI	Ti 6Al-4V ELI
Abutment Coronal Surface Coating	Zirconium Nitride (ZrN)	Zirconium Nitride (ZrN)	Titanium Nitride (TiN)
Denture Housing	Titanium	Titanium	Titanium
Nylon Insert	Polynil® (polyamide 6.6) or Vestamid®	Polynil® (polyamide 6.6) or Vestamid®	Nylon
Reprocessing			
Abutment	End user steam sterilization	End user steam sterilization	End user steam sterilization
Denture Housing	Titanium: End user steam sterilization	End user steam sterilization	End user steam sterilization
Nylon Insert	Polynil: Disinfectant Vestamid: End user steam sterilization	Polynil: Disinfectant Vestamid: End user steam sterilization	Not included

The indications for use of the subject device abutments are identical to the predicate device K251547, with the exception of the table of compatibilities. Both are intended for use with endosseous dental implants to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. All OEM device compatibilities included in the subject device indications for use were included in the primary predicate, but not all primary predicate compatibilities are included in the subject system.

The subject device consists of abutments for attachment of prostheses to endosseous implants similar to predicate devices. The subject device is similar in its indication for use, sizes, shapes, and surface coating. It is identical the predicate devices in coronal geometry such that the mechanism for overdenture retention is the same and similar angled design as reference device K233587. The ability of the attachment system to accommodate abutment divergence is similar to the reference device K233587. The diameters offered are same to those of the predicate devices and are dependent on the implant compatibility.

All DESSLoc abutments have the same coronal ridge retention design that attaches to the overdenture component by an interference (snap) fit similar to that of the predicate device. Retention inserts are fixed within a denture housing which is embedded in an overdenture prosthesis. The retention inserts allow for varying levels of retention similar to the reference device K233587. This connection allows the denture to be retained on the abutments while the majority of loading is supported by the contact of the denture with the gingival tissue surrounding the mandibular and maxillary ridges.

The subject device abutments are manufactured from the same material, titanium alloy, and have same surface coating that are applied above the implant/abutment interface. The zirconium nitride (ZrN) coating is the same the predicate devices with a thickness of approximately 2 and 3 μm. As with the primary predicate device, the coating is non-porous, the surface roughness of the machined abutment surface is maintained, and the coating is not applied to enhance tissue attachment to the device. 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 subject device denture housing is manufactured from titanium, the same material as the primary predicate K251547. The nylon inserts (Polynil® (polyamide 6.6) or Vestamid® Care ML GB30 (polyamide 12)) are the same components previously cleared under K251547. The subject device denture housing and retention inserts are provided non-sterile to the end user for the end user to sterilize or disinfect prior to use, the same as the primary predicate.

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.