June 11, 2026

Smart Denture Conversions, LLC
% Joseph Azary
Regulatory Consultant
Aztech Regulatory & Quality, LLC
543 Long Hill Ave.
Shelton, Connecticut 06484

Re: K254145
Trade/Device Name: Omni-Directional Multi-Unit Abutment System (Trade Name: Omnibut™)
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 13, 2026
Received: May 13, 2026

Dear Joseph Azary:

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)*
K254145

Device Name
Omni-Directional Multi-Unit Abutment System (Trade Name: Omnitbut™)

Indications for Use *(Describe)*
The Omnibut is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Compatible Implant Systems

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
BioHorizons (Internal Hex)	3.8, 4.6	3.5
Hiossen ET (Internal Hex)	3.5, 4.0	Mini (2.1)
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular (2.5)
MegaGen AnyRidge (Internal Hex)	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0	3.5
Neodent GM Helix Neodent GM Drive Neodent GM Max (Morse taper GM)	3.5,3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM (3.0)
NobelActive® NobelParallel Conical NobelReplace Conical (Conical Connection)	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
Southern Implants Provata (Internal Hex)	3.75, 4.0, 4.2, 5.0, 6.0, 7.0, 8.0, 9.0	3.5
Southern Implants SP1 (Conical Connection)	3.5, 4.0, 5.0	SP1 (3.0)
Straumann BLX Straumann BLC (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Tatum Surgical Integrity (Internal Pentagon)	3.7-4.5	3.7
	5.0	5.0
	6.0-8.0	6.0
Zimmer Tapered Screw-Vent ® (Internal Hex)	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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Smart Denture Conversions, LLC

Omni-Directional Multi-Unit Abutment System

ADMINISTRATIVE INFORMATION

Date Prepared:	June 10, 2026
Manufacturer Name:	Smart Denture Conversions, LLC 1800 N. Salem St., Suite 104 Apex, NC 27523
FDA Registration:	3015527825
Telephone:	(855) 550-0707
Representative/Consultant:	Joseph Azary Aztech Regulatory & Quality LLC 543 Long Hill Ave Shelton, CT 06484 Telephone: (203) 242-6670 Email: jazary@aztechregulatory.com

DEVICE NAME AND CLASSIFICATION

Proprietary Name:	Omni-Directional Multi-unit Abutment System (Trade Name: Omnibut™)
Common/Usual 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
510(k) Type:	Abbreviated 510(k)

PREDICATE AND REFERENCE DEVICE INFORMATION

Primary Predicate:

K242064, Omni-Directional Multi-unit Abutment System (Trade Name: Omnibut™), Smart Denture Conversions, LLC

Reference Devices:

K240208, DESS Dental Smart Solutions, Terrats Medical SL
K232418, Single Platform SP1 Implant Solution, Southern Implants Ltd
K180465, Provata Implant System, Southern Implants Ltd
K213576, Tatum Surgical Dental Implant System, Tatum Surgical

Reference Devices for OEM Implant Body Clearances:

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.
K071370, Nobelactive Internal Connection Implant, Nobel Biocare AB
K083205, Nobelactive 8.5 Mm & 18.0 Mm, Nobel Biocare AB
K142260, NobelActive®, Nobel Biocare AB

K161416, NobelActive Multi Unit Plus Abutment, 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
K230108, Straumann® BLC and TLC Implants, Institut Straumann AG
K072589, Tapered Screw-Vent Implant, 4.1mmD, Zimmer Dental, Inc.
K061410, Screw-Vent Implant System, SV, Tapered Screw-Vent Implant System TSV. Advent Implant System AV, Zimmer One Piece Implant, Zimmer Dental (includes 3.7, 4.7 and 6.0mm diameters)
K071638, BioHorizons Tapered Internal Implant System, BioHorizons Implant Systems, Inc.
K103691, BioHorizons Abutment System, BioHorizons Implant Systems, Inc.
K121787, BioHorizons Tapered Internal Plus Implants, BioHorizons Implant Systems, Inc.
K172576, BioHorizons Tapered Short Implants, BioHorizons Implant Systems, Inc.
K223697, MRI for BioHorizons Implants and Abutments, BioHorizons Implant Systems, Inc.
K140091, MegaGen AnyRidge Implant System, MegaGen Implant Company, Limited
K122231, Xpeed Any Ridge Internal Implant System, MegaGen Implant Company, Limited
K140934, Hiossen Implant System, Hiossen Inc.
K222636, Hiossen ET Abutment System, Hiossen Inc.
K191054, Southern Implants MAX Implant System, Southern Implants Ltd
K222457, Provata Implant System, Southern Implants (Pty), Ltd
K110955, Anyridge Internal Implant System, Megagen Co, Ltd
K240187, Tapered Pro Conical Implant System, Biohorizons Implant Systems Inc
K133592, Neodent Implant System, Titamax Ti Ex Acqua and Ti Drive Acqua,
Titamax Smart Ex Acqua Dand Drive Smart Acqua, Titamax CM

INTENDED USE/INDICATIONS FOR USE STATEMENT

Indications for Use:

The Omnibut is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.

Compatible Implant Systems

Compatible Implant System (Connection)	Implant Body Diameter, mm	Implant Platform, mm
BioHorizons (Internal Hex)	3.8, 4.6	3.5
Hiossen ET (Internal Hex)	3.5, 4.0	Mini (2.1)
	4.0, 4.5, 5.0, 5.5, 6.0, 7.0	Regular (2.5)
MegaGen AnyRidge (Internal Hex)	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0	3.5
Neodent GM Helix Neodent GM Drive Neodent GM Max (Morse taper GM)	3.5,3.75, 4.0, 4.3, 5.0, 6.0, 7.0	GM (3.0)
NobelActive®(Conical Connection)	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
NobelReplace Conical (Conical Connection)	3.5	NP (3.5)
	4.3, 5.0	RP (3.9)
NobelParallel Conical (Conical Connection)	3.75	NP (3.5)
	4.3, 5.0	RP (3.9)

Southern Implants Provata (Internal Hex)	3.75, 4.0, 4.2, 5.0, 6.0, 7.0, 8.0, 9.0	3.5
Southern Implants SP1 (Conical Connection)	3.5, 4.0, 5.0	SP1 (3.0)
Straumann BLX (TorcFit™ Internal Hexalobular)	3.5, 3.75, 4.0, 4.5	RB
	5.0, 5.5, 6.5	WB
Straumann BLC (TorcFit™ Internal Hexalobular)	3.75	RB
	4.5, 5.5, 6.5	WB
Tatum Surgical Integrity (Internal Pentagon)	3.7-4.5	3.7
	5.0	5.0
	6.0-8.0	6.0
Zimmer Tapered Screw-Vent ® (Internal Hex)	3.7, 4.1	3.5
	4.7	4.5
	6.0	5.7

Intended Use:

Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Omnibuts, in combination with four or more endosseous implants, are indicated for multiple unit reconstructions when screw-retained prosthetics are preferred.

SUBJECT DEVICE DESCRIPTION

The Omnibut™ is a transmucosal abutment used to support screw-retained prostheses on four or more implants. The subject device has a premanufactured connection for the platforms listed in ***Compatible Implant Systems table***.

The system involves a ball abutment attached to an implant. A retention attachment allows for angle corrections of up to 30° off the implant axis. The ball abutment is inserted into the implant, then, the attachment is adjusted to the desired angle using an orientation screw. The abutment supports prostheses that connect via titanium cylinders, which are incorporated into resin or ceramic prostheses. Finally, the prostheses are retained to the abutment by prosthetic screws.

The subject device abutments and system components are manufactured from Ti-6Al-4V alloy conforming to ASTM F136. The subject device is a single use device. The device is provided nonsterile and intended to be sterilized by the user prior to placement in the patient.

PERFORMANCE DATA

Non-clinical testing performed on the subject device to demonstrate substantial equivalence included:

- Reverse engineering dimensional analysis of OEM implants, OEM abutments, OEM retaining screws, and OEM abutment/screw assemblies for Hiossen ET Mini and Regular, MegaGen AnyRidge, and BioHorizons Internal systems to confirm dimensional compatibility with the Omnibut abutments.
- Dimensional compatibility verification using OEM-supplied engineering drawings with tolerances for Tatum Integrity, Southern Implants SP1, and Southern Implants Provata systems to confirm interface fit with the Omnibut abutments.
- Dynamic loading (fatigue) testing in accordance with ISO 14801:2016 and FDA's Dynamic Loading Test criteria on worst-case Omnibut–implant constructs for each new compatible implant system to determine Maximum Endured Load (MEL) and demonstrate that all new configurations meet or exceed the applicable performance thresholds.
- Dynamic loading (fatigue) testing in accordance with ISO 14801:2016 and FDA's Dynamic Loading Test criteria on the 3.8mm gingival height Omnibut configuration to demonstrate that higher gingival height designs exhibit MEL values equal to or greater than their corresponding standard-height abutments.
- Bench testing of screw components to verify mechanical integrity, proper function within the Omnibut assembly, and secure retention of the prosthesis.
- Referenced from K242064 was a non-clinical worst-case analysis to evaluate the subject device 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 May 2021) including magnetically induced displacement force and torque;

- Referenced from K242064 was moist heat steam sterilization validation, performed using an overkill method per ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO TIR 17665-2, which demonstrated a Sterility Assurance Level (SAL) of 10^{-6} for the worst-case Omnibut assembly and remains bounding for the expanded product line.
- Referenced from K242064 was cytotoxicity testing per ISO 10993-5 and a biocompatibility risk assessment per ISO 10993-1 of the final device, which demonstrated no cytotoxic potential and established material biocompatibility for the system.
- Referenced from K242064 was retention (push-out) testing of the Omnibut ball–retention component interface.
- Referenced from K242064 was All-On-4 simulated-use fatigue testing of the Omnibut abutments and comparative testing with the K242064 predicate abutments.
- Referenced from K242064 was simulated cleaning (cleansability) testing under worst-case hygiene conditions.

Table 2 – Summary of Performance Data

Standard	Description of Test	Results
Reverse Engineering Dimensional Analysis FDA Guidance Document, ***"Endosseous Dental Implants and Endosseous Dental Implant Abutments – Performance Criteria for Safety and Performance Based Pathway"*** (Oct. 15, 2024)	Reverse engineering dimensional analysis of OEM implant bodies, OEM abutments, and OEM abutment screws were performed to demonstrate that the Omnibut abutments are compatible with the noted implant systems.	PASS – The engineering and dimensional analysis concluded that each Omnibut design is compatible with the applicable implant connection.
Dynamic Fatigue Testing ISO 14801:2016 FDA Guidance Document, ***"Endosseous Dental Implants and Endosseous Dental Implant* Abutments *– Performance Criteria for Safety and Performance Based Pathway"*** (Oct. 15, 2024)	Dynamic Fatigue testing per: ISO 14801:2016: Dentistry — Implants — Dynamic loading test for endosseous dental implants Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Class II Special Controls Guidance Document for Industry and FDA Staff Section 8	PASS – The results conclude that when evaluated in a manner consistent with ISO 14801:2016, the Omnibut met all predetermined acceptance criteria.
Bench Testing	Bench testing evaluated the mechanical performance and functional integrity of the Omnibut system and associated screws under simulated use conditions. Testing confirmed proper fit and seating, secure engagement with drivers and prosthetic components, and adequate strength and stability of the assemblies across all relevant configurations.	PASS – All screw samples met acceptance criteria, withstanding the specified torque and demonstrating proper seating and driver engagement within the test assembly.

MR Analysis Referenced from K242064 TO Woods, *"Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices,"* Journal of Testing and Evaluation, Vol. 49, No. 2, 2021, pp. 783-795	The MR Conditional analysis evaluated the worst-case assemblies using mass-based rationale and published data on Ti-6Al-4V ELI to confirm that the expanded product line remains within the previously validated MR safety limits and existing MR Conditional labeling.	PASS – Worst-case Omnibut–implant assembly mass remains well below the 200g limit evaluated in the Woods paper and uses the same ASTM F136 titanium alloy and MR labeling as in K242064.
Sterilization Validation Testing per standards: AAMI TIR12:2020 ANSI/AAMI/ISO 17665-1:2026/(R)2013 ANSI/AAMI ST79:2017	AAMI TIR12:2020 Designing, Testing, And Labeling Medical Devices Intended For Processing By Health Care Facilities: A Guide For Device Manufacturers, Overkill method according to Section 5.7	PASS – Results from testing have demonstrated that the Omnibut was able to achieve a 10^{-6} SAL when using the recommended parameters in the Instructions for Use (IFU).
Biological Risk Assessment Referenced from K242064 ISO 10993-1:2018 FDA Guidance on the Use of ISO 10993-1, 2023	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process	All biological endpoint testing performed on the device, along with the analysis on the physical and chemical information, returned passing results. All biological endpoint testing suggests that the Omnibut is biocompatible and does not present a foreseen biological risk to those patient populations it is intended for.
Cytotoxicity Referenced from K242064 ISO 10993-5:2009	Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity	The test article showed no evidence of causing cell lysis or toxicity. The test article met the requirements of the test since the grade was grade 0 (no reactivity).
Retention Force Testing Referenced from K242064	The Omnibut has a retention attachment. Retention Force testing was performed via tensile push-out to ensure that the attachment will not detach during clinical use.	PASS – The Omnibut retention attachment did not detach at a predetermined acceptable force.
Simulated-Use Testing Referenced from K242064	Simulated Use of four Omnibuts with components connected to a Titanium Bar under a clinically relevant cyclic load.	PASS – The Omnibut and components did not yield, deform, or fracture after fatigue testing.
Simulated-Use Cleaning Referenced from K242064	Simulated cleaning of Omnibuts in a fixture with a clinically worst case cleansibility construction. Cleaning performed six times.	PASS – All parts of the Omnibuts were clean of soil indicators after six soilage and cleaning cycles.

Clinical performance data is not required to establish substantial equivalence for the subject devices.

EQUIVALENCE TO MARKETED DEVICES

The subject device abutments are substantially equivalent in intended use to the primary predicate device K242064 and all Reference Devices. The subject abutments are intended for the same use as the primary predicate with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible.

Technologically, the subject devices share the same fundamental design characteristics as the primary predicate: omni-directional multi-unit abutments with internal implant–abutment interfaces, screw-retained prosthesis attachment, and abutment angulations ranging from straight to 30°. Abutment collar heights and platform diameters for the subject devices fall within the ranges already cleared for the primary predicate (K242064) and under Reference Device #1 (K240208).

The subject devices are manufactured from the same titanium alloy as the primary predicate and are supplied non-sterile for single-patient, single-use, consistent with K242064 and the relevant reference devices. No new materials, coatings, or fundamental changes to the method of fixation have been introduced.

The expanded range of implant system compatibilities for the subject abutments is supported by dimensional analysis, OEM drawings, and mechanical testing, and is consistent with the types of compatibilities previously cleared for the predicate and reference devices. Abutment collar heights for the subject devices are within the cleared range for the reference device K240208, and the subject abutments are compatible with the OEM implant bodies associated with the referenced systems.

Non-clinical performance testing, including dynamic fatigue testing in accordance with ISO 14801 and biocompatibility assessment in accordance with ISO 10993-1 and ISO 10993-5 (as referenced from K242064), demonstrates that the subject devices perform substantially equivalent to the predicate device.

The risks associated with the use of angled abutments and multi-unit restorations are mitigated by this mechanical testing and by adherence to the same materials, manufacturing processes, and risk controls as the predicate. Collectively, the data supports the conclusion that the subject devices are substantially equivalent to the marketed predicate.

CONCLUSION

The non-clinical performance data included in this submission demonstrate that the subject abutments are substantial equivalence to the predicate and reference devices. Overall, the subject devices are the same as the primary predicate in that they:

- Have the same intended use,
- Use the same operating principles and omni-directional multi-unit abutment concept,
- Incorporate the same basic abutment geometry and fixation method,
- Are manufactured from the same material using the same manufacturing and cleaning processes,
- Are supplied non-sterile for the same sterilization methods and validated steam sterilization instructions, and
- Use same packaging and single-patient, single-use labeling.

All other reference devices are included for compatible OEM implant systems.

The only changes introduced in this submission relate to expanded implant compatibilities and additional collar height options that are fully bounded by dimensional analysis and bench testing. These modifications do not alter the fundamental design, material, or performance characteristics established in K242064. On this basis, Smart Denture Conversions, LLC concludes that the subject devices therefore substantially equivalent to the predicate and reference devices summarized in Table 3, *Substantial Equivalence*.

Descriptive Information	Subject Device	Primary Predicate	Reference Device #1	Reference Device #2	Reference Device #3	Reference Device #4
	Omni-Directional Multi-Unit Abutment System Smart Denture Conversions	K242064 Omni-Directional Multi-Unit Abutment System Smart Denture Conversions	K240208 DESS Dental Smart Solutions Terrats Medical SL	K232418 Single Platform SP1 Implant Solution Southern Implants Ltd	K180465 Provata Implant System Southern Implants Ltd	**K213576** Tatum Surgical Dental Implant System Tatum Surgical
Registration #	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630
Registration Title	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment
Regulation Class	II	II	II	II	II	II
Product Code	NHA	NHA	NHA	NHA	NHA	NHA
Reason for predicate or reference	N/A	Abutment designs, technology, function, retention testing, compatibilities, materials, manufacturing, biocompatibility	Implant System Compatibility, Gingival Height	Implant System Compatibility	Implant System Compatibility	Implant System Compatibility

Device	Intended Use Statement	Indications for Use Statement
Subject Device Omni-Directional Multi-Unit Abutment Smart Denture Conversions LLC	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Omnibuts, in combination with four or more endosseous implants, are indicated for multiple unit reconstructions when screw-retained prosthetics are preferred.	The Omnibut is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. [Table of Compatible Implants]
Primary Predicate Device K242064 Omni-Directional Multi-Unit Abutment Smart Denture Conversions LLC	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Omnibuts, in combination with four or more endosseous implants, are indicated for multiple unit reconstructions when screw-retained prosthetics are preferred.	The Omnibut is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. [Table of Compatible Implants]
Reference Device #1 K240208 DESS Dental Smart Solutions Terrats Medical SL	Functional and esthetic rehabilitation of the edentulous mandible or maxilla.	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. [Table of Compatible Implants]
Reference Device #2 K232418 Compact Conical Abutment Southern Implants Ltd	The Compact Conical Abutments are intended to be used in the Maxilla or Mandible connected to an endosseous dental implant to support multiple-unit screw retained prosthetic restorations. These abutments extend the prosthetic interface above the implant platform interface (i.e. to tissue-level).	The Conventional Abutments and Prosthetic Screws are premanufactured prosthetic components directly connected to endosseous dental implants and intended for use in fully edentulous or partially edentulous maxilla and/or mandible to provide support for crowns, bridges or overdentures.
Reference Device #3 K180465 Compact Conical Abutment Southern Implants Ltd	The Compact Conical Abutments are intended to be used in the Maxilla or Mandible connected to an endosseous dental implant to support multiple-unit screw retained prosthetic restorations. These abutments extend the prosthetic interface above the implant platform interface (i.e. to tissue-level).	These devices are premanufactured prosthetic components directly connected to endosseous dental implants and intended for use in fully edentulous or partially edentulous maxilla and/or mandible to provide support for crowns, bridges or overdentures.
Reference Device #4 K213576 Multi-Unit Abutment Tatum Surgical	The Tatum Surgical Integrity Tapered, “T” and “S” Dental Implant Systems are intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prothesis to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.	The Integrity Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for removable or fixed prothesis to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
Comparison	Same as primary predicate.	Same as primary predicate, except new compatibilities listed in table.

	Subject Device	Primary Predicate	Reference Device #1	Reference Device #2	Reference Device #3	Reference Device #4	Comparison
510(k) Number	N/A	N/A	K240208	K232418	K180465	K213576	N/A
Device Name	**Omni-Directional Multi-Unit Abutment** For Omni-Directional Multi-Unit Abutment System	**Omni-Directional Multi-Unit Abutment** For Omni-Directional Multi-Unit Abutment System	**Multi-Unit Abutment** For DESS Dental Smart Solutions	**Compact Conical Abutment** For Single Platform SP1 Implant System	**Compact Conical Abutment** For Provata Implant System	**Multi-Unit Abutment** For Tatum Surgical Implant System	N/A
Design							N/A
Compatibility	BioHorizons Internal, Hiossen ET, MegaGen AnyRidge, Neodent Grand Morse, NobelActive®, NobelParallel Conical, NobelReplace Conical, Southern Implants SP1 and Provata, Straumann TorcFit™, Tatum Integrity, Zimmer Tapered Screw-Vent®	Neodent Grand Morse, NobelActive®, Straumann TorcFit™, Zimmer Tapered Screw-Vent®	Astra Tech EV, Astra Tech OsseoSpeed, BioHorizons Internal, Biomet 3i OSSEOTITE®, Dentium Superline, DESS Active, PrimaConnex, Genesis, Molaris, Paltop, MIS Seven, MIS M4, MegaGen AnyRidge, Neodent Grand Morse, NobelActive®, NobelParallel Conical, NobelReplace Conical, NobelReplace® Trilobe, Nobel Brånemark System®, Osstem TS, Hiossen ET, Straumann TorcFit™, Straumann® Bone Level, Straumann® Tissue Level, Zimmer Screw Vent®/Tapered Screw-Vent®, TSX™ Implant System	Southern Implants SP1	Southern Implants Provata	Tatum Integrity	Same connections as Predicate. Additional connections supported by Reference Devices #1-4.
Prosthesis Attachment	Screw Retained	Screw Retained	Screw Retained	Screw Retained	Screw Retained	Screw Retained	Same as Primary Predicate
Restoration	Multi-Unit	Multi-Unit	Single and Multi-Unit	Multi-Unit	Multi-Unit	Multi-Unit	Same as Primary Predicate
Abutment Collar Height	2.3mm-3.8mm	2.3mm	1.0mm-5.5mm	1.5mm-4.5mm	1mm-5mm	1.4-1.5mm	Similar. Height is within cleared range of Primary Predicate and Reference Device #1.

Platform Diameter	4.8mm	4.8mm	4.8mm	4.8mm	4.8mm	5.0mm	Same as Primary Predicate
Abutment Angle	Straight to 30°	Straight to 30°	Straight to 30°	0°, 17° and 30°	0°, 20° and 30°	0°, 20° and 30°	Same as Primary Predicate
Abutment Material	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V	Titanium alloy (ASTM F136)	Titanium alloy (ASTM F136)	Same as Primary Predicate
Abutment Fixation	Abutment fixation with an integral screw	Abutment fixation with an integral screw	Abutment fixation with integral screw or retaining screw	Abutment fixation with integral screw or retaining screw	Abutment fixation with integral screw or retaining screw	Abutment fixation with integral screw or retaining screw	Same as Primary Predicate
Abutment/ Implant Interface	Internal	Internal	Internal, External	Internal	Internal	Internal	Same as Primary Predicate
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same as Primary Predicate
Usage	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Same as Primary Predicate
Fatigue Testing	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Same as Primary Predicate
Biocompatibility	Biocompatible according to ISO 10993-1: 2018	Biocompatible according to ISO 10993-1: 2018	Biocompatible according to ISO 10993-1: 2018	Biocompatible according to ISO 10993-1: 2018	Biocompatible according to ISO 10993-1: 2018	Biocompatible according to ISO 10993-1: 2018	Same as Primary Predicate