June 20, 2023

Implant Direct Sybron Manufacturing LLC
Reina Choi
Senior Regulatory Affairs Manager
3050 East Hillcrest Drive
Thousand Oaks, California 91362

Re: K223535
Trade/Device Name: SMARTbase Abutment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: May 19, 2023
Received: May 22, 2023

Dear Reina Choi:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223535

Device Name

SMARTbase Abutment System

Indications for Use *(Describe)*

The SMARTbase Abutment System is designed to be used in support of a dental implant(s) to provide support for prosthetic restorations in a partially or fully edentulous patient. The SMARTbase Abutment System is intended for use in the mandible or maxilla in support of single or multiple unit restorations.

The SMARTbase Abutment System integrates multiple components for use in both a traditional and digital dentistry workflow: scan files from Intra-oral Scanners and lab scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The SMARTbase Abutment System consists of two major parts: the titanium base and zirconia top components make up a two-piece abutment.

- SMARTbase abutment for narrow (3.2mmD) Legacy implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
- SMARTbase abutment for short (8mm) 3.7mmD Legacy implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.
- SMARTbase abutment for narrow diameter (3.2. 3.3mm) InterActive implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements or denture stabilization.

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

K223535

i. Submitter Information

Submitter:	Implant Direct Sybron Manufacturing LLC 3050 E. Hillcrest Drive Thousand Oaks, CA 91362, USA
Contact Person:	Reina Choi, Senior Regulatory Affairs Manager
E-Mail:	Reina.choi@envistaco.com
Telephone Number:	(818) 307-3132
Prepared By:	Reina Choi
Date Prepared	16 June 2023

ii.Device Name

Proprietary name:	SMARTbase Abutment System
Manufacturer:	Implant Direct Sybron Manufacturing LLC
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Device Class:	II
Product Code:	NHA (Primary), PNP (Secondary)

iii. Predicate Devices

Primary Predicate Device

Propriety Name:	Legacy™ SMARTBase Abutments (K191458)
Manufacturer:	Implant Direct Sybron Manufacturing LLC
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Device Class:	Class II
Product Code:	NHA, PNP

Reference Device #1

Propriety Name:	InterActve™ SMARTBase Abutment
(K181359) Manufacturer:	Implant Direct Sybron Manufacturing LLC
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Device Class:	Class II
Product Code:	NHA, PNP

Reference Device #2

Proprietary Name:	3Shape Abutment Designer™ Software (K151455)
Manufacturer:	3Shape A/S
Common Name:	Dental Abutment Design Software for Dental Laboratory
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Product Code:	PNP

Reference Device #3

Proprietary Name:	Spectrum System (K061319)
Manufacturer:	Implant Direct Sybron Manufacturing LLC
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Product Code:	NHA

Reference Device #4

Proprietary Name:	Spectrum-System Abutments 2008 (K081101)
Manufacturer:	Implant Direct Sybron Manufacturing LLC
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Product Code:	NHA

Reference Device #5

Proprietary Name:	ExocadAbutmentCAD (K193352)
Manufacturer:	Exocad GmbH
Common Name:	Dental Abutment Design Software for Dental Laboratory
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Product Code:	PNP

Reference Device #6

Proprietary Name:	DESS Dental Smart Solutions (K222288)
Manufacturer:	Terrats Medical SL
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Product Code:	NHA

Reference Device #7

Proprietary Name:	Titanium Abutment Blank Nobel Biocare N1 TCC (K223677)
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR§872.3630
Regulatory Class:	II
Product Code:	NHA, PNP

iv. Device Description

The SMARTbase Abutment System is a two-piece engaging and non-engaging dental implant abutment comprised of a titanium base and a zirconia top (which can be supplied with the base or acquired separately by the customer). There are three device lines offered in the SMARTbase Abutment System: Legacy™ SMARTbase Abutment, InterActive™ SMARTbase Abutment, and SMARTbase Cylinder.

The abutments are offered in three widths (narrow, regular, and wide), platform diameters of 3.0mm, 3.5mm, 4.5mm and 5.7mm for Legacy™ and 3.0mm, 3.4mm for InterActive™, and collar (titanium base) heights of 0.25, 1.0, and 2.0 mm in order to accommodate different patient anatomies. The SMARTbase Cylinder is a two-piece non-engaging dental implant and multi-unit abutment cylinder comprised of a titanium base and a zirconia top (which can be supplied with the base or acquired separately by the customer). The SMARTbase Cylinder is offered in two heights 9.0mm (that can be shortened to 4.0mm) and 4.0mm and in one width, platform diameters and collar (titanium base) height in order to accommodate different patient anatomies.

Table 0-1 Design Specifications for SMARTbase Abutment System

	Legacy™ SMARTbase Abutment	**InterActive™ SMARTbase Abutment**	**SMARTbase Cylinders**
Platform Diameter	3.0mm, 3.5mm, 4.5mm, and 5.7mm	3.0mm and 3.4mm	5.0mm
Titanium Base Height	4mm and 6.6mm	4mm and 6.6mm	4mm and 9mm
Coronal Width	Narrow, Regular, Wide	Extra-narrow, Narrow, Regular, and Wide	N/A
Abutment Collar Height*	0.25, 1, 2mm	1 and 2mm	0.25mm
Abutment Angulation	0 to 30 degrees	0 to 30 degrees	0 to 30 degrees
Abutment Post Height	4mm minimum	4mm minimum	4mm minimum
Zirconia Wall Thickness	Single Unit: Wall thickness	Single Unit: Wall thickness	Single Unit: Wall thickness

	circular: 0.9mm minimum Multiple Unit: 2mm	circular: 0.9mm minimum Multiple Unit: 2mm	circular: 0.9mm minimum Multiple Unit: 2mm

* the “Abutment Collar Height” values are provided by the titanium base component for the two-piece SMARTbase Abutment System.

The subject device is supplied with fixation screws that function as an extension of the implant or multi-unit abutment to which the SMARTbase Abutment or SMARTbase Cylinder is secured and is used with several accessories in digital workflows to fabricate the patient-specific restorations, including scan adapters, implant analogs, and off-axis tools.

The available design options for the zirconia top components to be provided either as a superstructure (to then receive a separate crown or bridge) or hybrid abutment-crown. There are three workflow options for fabricating the zirconia top component which fits the titanium abutment base:

(1) end user creation of a press-ceramic material by conventional wax-up technique,

(2) Implant Direct design and milling of zirconia in stock sizes using ceramic material of ZirCAD Prime (K142233) and provision of same to the end user, and

(3) digital workflow using 3Shape or Exocad software where CAD design and milling of the superstructure or hybrid crown component is done at the end user’s dental laboratory/office; the CAD design requires loading of Implant Direct’s abutment design library to the 3Shape or Exocad software to design the superstructure or hybrid crown component within the established design limitations and specifications. The digital workflow includes use of the following products (not subject devices of this submission):

- Ceramic material: ZirCAD Prime (K142233)
- Cement: Maxcem Elite Self-Etch/Self-Adhesive Resin Cement (K060469)
- Composite: Kerr Harmonized (K151332)
- Intra oral scanners: Medit Scanner, ITero Scanner Trios Scanner, CareStream Scanner
- Abutment design software: 3Shape Abutment Designer™ Software (K151455) and Exocad AbutmentCAD Software (K193352)
- Milling machine: Wieland-Zenotec Select, Zenotec CAM, iCAM V5, and imes icore

In compliance with the FDA Guidance Document titled, “Bundling Multiple Devices or Multiple Indications in a Single Submission,” issued June 22, 2007, Implant Direct has prepared a single submission for the SMARTbase Abutment System as the supporting data is relevant to the SMARTbase Abutment System as a whole, and one review group will be involved.

v. Principle of Operation / Mechanism of Action

The abutment is mechanically connected to an endosseous implant via screw or cement for tooth replacement to restore chewing function. The abutments allow for patient-specific designs through conventional and digital restoration materials and methods. The final restorations are designed and produced under the direction of a clinical professional and are based on requirements provided to Implant Direct or the preferred laboratory in digital or stone model form. The restoration (crown) is designed to fit on top of the SMARTbase abutment using off-the-shelf 3Shape software (K151455) or Exocad software (K193352).

vi. Compatible Devices and Accessories

The SMARTbase Abutment System is intended to be used with the following previously cleared or exempt accessories/devices from Implant Direct below.

Table 0-2 – Compatible Implants and Auxiliary Accessories for SMARTbase Abutment System

Product Name	Product Code	Regulation #	Device Class	510(k) Clearance
InterActive™, SwishActive™ and simply InterActive™ Implants	DZE	872.3640	II	K130572 K143011
Simply Iconic™ Implants	DZE	872.3640	II	K210553
InterActive™ Abutments	NHA	872.3630	II	K130572
ScrewIndirect™ Implants	DZE	873.3640	II	K080633
Legacy™ Implants	DZE	873.3640	II	K192221 K073033
Legacy™ MUA	NHA	872.3630	II	K090234 K060063 K061319
InterActive™ MUA	NHA	872.3630	II	K153509
Fixation Screw	NHA	873.3630	II	K181359 K192458
Scan Adapter	NDP	872.3980	I	EXEMPT
Castable Coping	NDP	872.3980	I	EXEMPT
Implant Analog	NDP	872.3980	I	EXEMPT
Off-axis Tools	NDP	872.3980	I	EXEMPT

vii. Patient Contacting Components

Following the assessment set forth in ISO 10993-1:2018 Biological Evaluation of Medical Devices, Annex A, it was determined that the devices in scope of this submission do contain patient contacting components. The patient contacting components have direct patient contact components for a permanent duration of time (>30 days).

Table 0-3 – Patient Contacting Materials

Product Name	Material Description	Colorant
SMARTbase Abutment System	Titanium 6AL4V ELI (ASTM F136 / ISO 5832-3) and Zirconia	N/A
Fixation Screw	Titanium	N/A

viii. Indications for Use

The SMARTbase Abutment System is designed to be used in support of a dental implant(s) to provide support for prosthetic restorations in a partially and fully edentulous patient. The SMARTbase Abutment System is intended for use in the mandible or maxilla

in support of single or multiple unit restorations.

The SMARTbase Abutment System integrates multiple components for use in both a traditional and digital dentistry workflow: scan files from Intra-oral Scanners and lab scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The SMARTbase Abutment System consists of two major parts: the titanium base and zirconia top components make up a two-piece abutment.

- SMARTbase abutment for narrow (3.2mmD) Legacy implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
- SMARTbase abutment for short (8mm) 3.7mmD Legacy implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.
- SMARTbase abutment for narrow diameter (3.2. 3.3mm) InterActive implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements or denture stabilization.

ix. Summary of Substantial Equivalence

The similarities and differences between the Subject Device the SMARTbase Abutment System and the Predicate Device/Reference Devices as described in Table 3-0 are as follows:

- The Intended Use and Principle of Operation of the Subject Device and the Primary Predicate are the same. Both devices are used for supporting tooth replacements to restore chewing function.
- The Indications for Use of the Subject Device and the Primary Predicate is the similar except the subject device has a stand-alone compatibility section in the Instructions for Use. Both devices are prosthetic abutments that are directly connected to endosseous dental implants as an aid in prosthetic rehabilitation.
- The technological characteristics of the Subject device and the Primary Predicate are same. Both devices are cement or screw retained 2-piece abutments that are composed of titanium base (made from titanium alloy Ti6Al4V ELI according to ASTM F136 and ISO 5832-3) with gold and pink anodization and zirconia top components to make up a 2-piece abutment.
- Both Subject Device and Reference Device#1 can be fabricated from conventional and digital workflows for single or multi-unit restoration with same modification parameters.
- Both Subject Device and Primary Predicate Device (Legacy Engagement Abutment) have same design specifications: abutment collar height: 0.25mm, 1mm, and 2mm and 30^0 maximum angulation, and minimum 4mm post height.
- The approach for non-clinical performance testing and software verification & validation is the same for the Subject Device and the Primary Predicate. Testing was conducted to confirm that the technological differences between the devices do not raise different questions of substantial equivalence. The test results support that the Subject Device met the performance specifications as intended.

There are no major differences however there are minor differences between the subject device and predicate devices including:

- Workflow components and specific limitations are described in Description, Compatibility, and Warnings sections of the IFU. This does not raise new questions of substantial equivalence.
- The Subject Device has additional device line SMARTbase Cylinder that is compatible with implant and multi-unit abutments. This has been demonstrated by fatigue testing and thus does not raise new question of substantial equivalence.
- The Subject Device integrates different ceramic and cement materials, additional abutment design software, scanners, and milling machines to fabricate zirconia top component. This does not raise different questions of substantial equivalence as demonstrated by non-clinical performance testing and software verification & validation testing that the device can perform as intended.

Conclusion:

Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, the SMARTbase Abutment system is deemed to be substantially equivalent to the Predicate/Reference Devices as it satisfies all criteria of substantial equivalence and does not raise new concerns regarding substantial equivalence: Indications for Use, Technological Characteristics and Performance Data. The difference does not introduce a fundamentally new scientific technology and the nonclinical tests demonstrate that the device is substantial equivalent.

Table 0-4: SMARTbase Abutment System Comparison Table

Descriptive Information	Subject Device SMARTbase Abutment System (K223535)	Primary Predicate Legacy™ Engaging SMARTBase Abutments (K191458)	Reference Device#1 InterActive™ SMARTBase Abutment (K181359)	Reference Device#2 3Shape Abutment Designer™ Software (K151455)	Reference Device#3 Spectrum System (K061319)	Reference Device#4 Spectrum-System Abutments 2008 (K081101)	Reference Device #5 Exocad AbutmentCAD (K193352)	Reference Device #6 DESS Dental Smart Solutions (K222288)	Reference Device #7 Titanium Abutment Blank Nobel Biocare N1 TCC (K223677)	Comparison
Manufacturer	Implant Direct	Implant Direct	Implant Direct	3Shape A/S	Implant Direct	Implant Direct	Exocad GmbH	Terrats Medical SL	Nobel Biocare	Same
Pictorial Representation				N/A			N/A			N/A
Regulatory Classification										
Regulation #	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same
Regulation 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	Endosseous dental implant abutment	Endosseous dental implant abutment	Endosseous Dental Implant Abutment	Same
Regulation Class	II	II	II	II	II	II	II	II	II	Same
Product Code	NHA, PNP	NHA, PNP	NHA, PNP	PNP	NHA	NHA	PNP	NHA	NHA, PNP	Same
Indications for Use/Intended Use										
Indications for Use	The SMARTbase Abutment System is designed to be used in support of a dental implant(s) to provide support for prosthetic restorations in a partially or fully edentulous patient. The	The Legacy™ SMARTbase Abutment system is designed to be used in support of a dental implant(s) to provide support for prosthetic restorations in a partially edentulous patient.	InterActive/SwishActive Implant System consists of two-piece implants for one- stage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple- unit	The 3Shape Abutment Designer Software is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. The 3Shape Abutment Designer Software is intended for use by a dental	The Spectra Dental Implant System consists of one-piece or two-piece implants for single-stage or two- stage surgical procedures that are intended for use in partially or fully edentulous	Spectra-System Abutments are designed to be used in support of a dental implant(s) to provide support for prosthetic restorations such as crowns, bridges, overdentures or custom prosthetic fabrications in a partially or	The AbutmentCAD module is intended as an aid to the restoration of chewing function in partially or fully edentulous mandibles and maxillae. AbutmentCAD is a software device intended	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	Titanium Abutment Blank Nobel Biocare N1™ TCC is a premanufactured prosthetic component directly connected to an endosseous dental implant and is indicated for use as an aid in prosthetic	Same – Proposed, predicate, and reference devices are indicated for use with dental implants to provide support for single unit or multiple unit prosthetic restorations for partially or fully edentulous patients in the mandible or maxilla.

Descriptive Information	Subject Device SMARTbase Abutment System (K223535)	Primary Predicate Legacy™ Engaging SMARTBase Abutments (K191458)	Reference Device#1 InterActive™ SMARTBase Abutment (K181359)	Reference Device#2 3Shape Abutment Designer™ Software (K151455)	Reference Device#3 Spectrum System (K061319)	Reference Device#4 Spectrum-System Abutments 2008 (K081101)	Reference Device #5 Exocad AbutmentCAD (K193352)	Reference Device #6 DESS Dental Smart Solutions (K222288)	Reference Device #7 Titanium Abutment Blank Nobel Biocare N1 TCC (K223677)	Comparison
	SMARTbase Abutment System is intended for use in the mandible or maxilla in support of single or multiple unit restorations. The SMARTbase Abutment System integrates multiple components for use in both a traditional and digital dentistry workflow: scan files from Intra-oral Scanners and lab scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The SMARTbase Abutment System consists of two major parts: the	Legacy SMARTBase engaging abutments are intended for use in the mandible or maxilla in support of single unit restorations. The Legacy SMARTBase Abutment system integrates multiple components for use in both a traditional & digital dentistry workflow: scan files from Intra-oral Scanners & lab scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The Legacy SMARTbase system consist of two major parts: the titanium base and zirconia top components make up a two-piece abutment.	restorations and terminal or intermediate SMARTBase support for fixed bridgework. The system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The SMARTBase Abutments consist of two major parts. Specifically, the titanium base and zirconia top components make up a two- piece abutment. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.	practitioner or dental laboratory staff for designing the patient specific component of a two-piece, one-piece, or hybrid dental implant abutment. The single or multi-unit abutment design is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.	mandibles and maxillae, in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. They may be placed in immediate function if initial implant stability can be established. The Screw Indirect implant is indicated for the support and retention of bar overdentures or as a terminal or intermediary attachment for screw-retained fixed bridgework. It is indicated for immediate functional loading when four or more implants are splinted together in the edentulous	completely edentulous patient. Spectra-System Abutments are intended for use in the mandible or maxilla. Prostheses can be screw or cement retained to the abutment	to be used by trained professionals in dental practices or dental laboratories for the design of patient specific implant borne prosthetics such as one-piece abutments, two-piece/hybrid abutments, single or multi-unit screw-retained restorations. The design result is intended to be used by the manufacturer of an endosseous dental implant abutment to create the final device.	prosthetic restorations. All digitally designed custom abutments for use with Ti Base abutments or Pre-milled Blank abutments are to be sent to a Terrats Medical validated milling center for manufacture.	rehabilitation for single units and multiple units of up to three units The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, restoration material blanks, milling machine and associated tooling and accessories	Abutments are compatible with the same implants having the same platform sizes and thread sizes. The restorations are made using either a conventional or digital workflow.

Descriptive Information	Subject Device SMARTbase Abutment System (K223535)	Primary Predicate Legacy™ Engaging SMARTBase Abutments (K191458)	Reference Device#1 InterActive™ SMARTBase Abutment (K181359)	Reference Device#2 3Shape Abutment Designer™ Software (K151455)	Reference Device#3 Spectrum System (K061319)	Reference Device#4 Spectrum-System Abutments 2008 (K081101)	Reference Device #5 Exocad AbutmentCAD (K193352)	Reference Device #6 DESS Dental Smart Solutions (K222288)	Reference Device #7 Titanium Abutment Blank Nobel Biocare N1 TCC (K223677)	Comparison
	titanium base and zirconia top components make up a two-piece abutment. •SMARTbase abutment for narrow (3.2mmD) Legacy implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. •SMARTbase abutment for short (8mm) 3.7mmD Legacy implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors. •SMARTbase abutment for narrow diameter (3.2. 3.3mm) InterActive implants: Indicated for	•Legacy SMARTbase abutment for narrow dimeter (3.2mmD) implants: Indicated for single- tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. •Legacy SMARTbase abutment for short (8mm) 3.7mmD implants: Not intended for tooth replacement of canines, pre-molars or molars.	•Narrow Diameter (3.2, 3.3mm) Implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements or denture stabilization.		upper or lower jaw. This implant model is not indicated for use with abutments, only with a 2mm extender.					

Descriptive Information	Subject Device SMARTbase Abutment System (K223535)	Primary Predicate Legacy™ Engaging SMARTBase Abutments (K191458)	Reference Device#1 InterActive™ SMARTBase Abutment (K181359)	Reference Device#2 3Shape Abutment Designer™ Software (K151455)	Reference Device#3 Spectrum System (K061319)	Reference Device#4 Spectrum-System Abutments 2008 (K081101)	Reference Device #5 Exocad AbutmentCAD (K193352)	Reference Device #6 DESS Dental Smart Solutions (K222288)	Reference Device #7 Titanium Abutment Blank Nobel Biocare N1 TCC (K223677)	Comparison
	single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements or denture stabilization.									
Compatibility	• Legacy™1: body diameter 3.7 – 5.7mm; platform diameter 3.5, 4.5, 5.7mm; implant length 8- 16mm, excluding 6mm length • Legacy™2, 3, 4, simplyLegacy2 & 3: body diameter 3.2 – 7.0mm; platform diameter 3.0, 3.5, 4.5, 5.7mm; implant length 8-16mm, excluding 6mm length •InterActive™: body diameter 3.2-5.0mm; platform	Legacy SMARTBase engaging abutments are compatible at the implant level with Legacy (3.0mm, 3.5mm, 4.5mm and 5.7mm platform diameter) implants, excluding 6mm length implants. *Legacy1: body diameter 3.7 – 5.7mm; platform diameter 3.5, 4.5, 5.7mm; implant length 8- 16mm, excluding 6mm length •Legacy2, 3, 4, simplyLegacy2 & 3: body diameter	InterActive SMARTBase abutments are compatible at the implant level with InterActive (3.0mm and 3.4mm Platform) and SwishActive (3.0mm and 3.4mm Platform) system implants. *InterActive: body diameter 3.2-5.0mm; platform diameter 3.0, 3.4mm; implant length 8- 16mm, excluding 6mm length *SwishActive: body diameter 3.3-4.8mm; platform diameter 3.0,	N/A	Screw Indirect Implants (5.0mm Platform), Legacy and InterActive MUAs (5.0mm Platform)	Screw Indirect Implant (5.0mm Platform), Legacy and InterActive MUAs (5.0mm Platform)	N/A	Ankylos C/X, Astra Tech EV, Astra Tech OsseoSpeed™ 3.0, BioHorizons, Biomet 3i Certain®, Biomet 3i OSSEOTITE®, Camlog, Dentium SuperLine, FRIADENT XiVE®, MegaGen AnyRidge, Neodent Grand Morse, NobelActive®, NobelParallel Conical, NobelReplace® Trilobe, Nobel Brånemark System®,	Narrow Platform (NP) Regular Platform (RP) N1 TiUltra TCC implants	Similar; the added compatibility information for device does not raise any safety and efficacy question as it is supported by fatigue test data.

Descriptive Information	Subject Device SMARTbase Abutment System (K223535)	Primary Predicate Legacy™ Engaging SMARTBase Abutments (K191458)	Reference Device#1 InterActive™ SMARTBase Abutment (K181359)	Reference Device#2 3Shape Abutment Designer™ Software (K151455)	Reference Device#3 Spectrum System (K061319)	Reference Device#4 Spectrum-System Abutments 2008 (K081101)	Reference Device #5 Exocad AbutmentCAD (K193352)	Reference Device #6 DESS Dental Smart Solutions (K222288)	Reference Device #7 Titanium Abutment Blank Nobel Biocare N1 TCC (K223677)	Comparison
	diameter 3.0, 3.4mm; implant length 8- 16mm, excluding 6mm length • SwishActive™: body diameter 3.3-4.8mm; platform diameter 3.0, 3.4mm; implant length 8- 16mm, excluding 6mm length ScrewIndirect™: body diameter 3.0-5.7mm; platform diameter 5.0mm; implant length 8-16mm Legacy™ Multi-unit Abutment: Abutment platform diameter 5.0mm; InterActive™ Multi-unit Abutment: Abutment platform diameter 5.0mm	3.2 – 7.0mm; platform diameter 3.0, 3.5, 4.5, 5.7mm; implant length 8- 16mm, excluding 6mm length	3.4mm; implant length 8- 16mm, excluding 6mm length					Osstem TS, Straumann BLX, Straumann® Bone Level, Straumann® Tissue Level, Zimmer Eztetic, Zimmer Screw Vent®/ Tapered Screw-Vent®, Zimmer Spline, Zimmer SwissPlus		
Technological Characteristics										
Interface Platform Diameter	Legacy: 3.0mm, 3.5mm, 4.5mm, and 5.7mm	3.0mm, 3.5mm, 4.5mm, and 5.7mm	3.0mm and 3.4mm	N/A	5.0mm	5.0mm	N/A	Zimmer Screw Vent®/ Tapered Screw-Vent® -	NP, RP	Same

Descriptive Information	Subject Device SMARTbase Abutment System (K223535)	Primary Predicate Legacy™ Engaging SMARTBase Abutments (K191458)	Reference Device#1 InterActive™ SMARTBase Abutment (K181359)	Reference Device#2 3Shape Abutment Designer™ Software (K151455)	Reference Device#3 Spectrum System (K061319)	Reference Device#4 Spectrum-System Abutments 2008 (K081101)	Reference Device #5 Exocad AbutmentCAD (K193352)	Reference Device #6 DESS Dental Smart Solutions (K222288)	Reference Device #7 Titanium Abutment Blank Nobel Biocare N1 TCC (K223677)	Comparison
	InterActive: 3.0mm, 3.4mm Cylinder: 5.0mm							3.5mm,4.5mm, 5.7mm, NobelActive NP and RP, Also, other identified manufacturer systems diameters and platforms in the 510k		
Interface Connection	Legacy: Internal hex connection InterActive: Internal hex conical connection Cylinder: External Flat connection	Internal hex connection	Internal hex conical connection	N/A	External Flat connection	External Flat connection	N/A	Zimmer Screw Vent®/ Tapered Screw-Vent® - Internal Hex NobelActive - Internal Conical Connection with internal hex	Trioval Conical connection	Same
Collar Height	Legacy: 0.25mm - 2.0mm InterActive: 1.0mm - 2.0mm Cylinder: 0.25mm	0.25mm – 2.0mm	1.0mm – 2.0mm	N/A	N/A	N/A	N/A	0.3mm-6mm	0.335 mm – 4.6mm	Same
Abutment Material and Surface Treatment	Titanium Alloy & Zirconia; abutments are titanium anodized gold and pink	Titanium Alloy & Zirconia; abutments are titanium anodized gold and pink	Titanium Alloy & Zirconia; abutments are titanium anodized gold and pink	N/A	Titanium Alloy	Titanium Alloy	N/A	Titanium Alloy	Titanium Alloy / Anodization	Same
Abutment Design	2-piece Abutment	2-piece Abutment	2-piece Abutment	N/A	2-piece Abutment	2-piece Abutment	N/A	2-piece Abutment	2-piece Abutment	Same

Descriptive Information	Subject Device SMARTbase Abutment System (K223535)	Primary Predicate Legacy™ Engaging SMARTBase Abutments (K191458)	Reference Device#1 InterActive™ SMARTBase Abutment (K181359)	Reference Device#2 3Shape Abutment Designer™ Software (K151455)	Reference Device#3 Spectrum System (K061319)	Reference Device#4 Spectrum-System Abutments 2008 (K081101)	Reference Device #5 Exocad AbutmentCAD (K193352)	Reference Device #6 DESS Dental Smart Solutions (K222288)	Reference Device #7 Titanium Abutment Blank Nobel Biocare N1 TCC (K223677)	Comparison
Abutment Fixation	Abutment fixation with a screw	Abutment fixation with a screw	Abutment fixation with a screw	N/A	Abutment fixation with a screw	Abutment fixation with a screw	N/A	Abutment fixation with a screw	Abutment fixation with a screw	Same
Restoration	Zirconia Single and multi-unit	Zirconia Single and multi-unit	Zirconia Single and multi-unit	N/A	Multi-unit denture	Multi-unit denture	N/A	Single and multi-unit	Single-unit and multi-unit (up to 3 units)	Same
Cement Adhesive	Maxcem Elite (K060469)	EMBRACE (K071278)	EMBRACE (K071278)	N/A	EMBRACE (K071278)	EMBRACE (K071278)	N/A	Multilink Hybrid Abutment Cement	N/A	Similar
Abutment Angle	≤30 degrees from implant axis	≤30 degrees from implant axis	≤30 degrees from implant axis	N/A	N/A	N/A	N/A	≤30 degrees from implant axis	≤30 degrees from implant axis	Same
Post Height	4.0mm minimum	4.0mm minimum	4.0mm minimum	N/A	4.0mm minimum	4.0mm minimum	N/A	4.0mm minimum	4.0mm minimum	Same
Prosthesis Attachment	Screw- or cement-retained	Screw- or cement-retained	Screw- or cement-retained	N/A	Screw retained overdenture	Screw retained	N/A	Screw- or cement-retained type restoration	Screw or cement-retained type restoration	Same
Design Workflow	Conventional and Digital	Conventional and Digital	Conventional and Digital	Digital	Conventional	Conventional	Digital	Digital	Digital	Same
Sterility	Supplied non-sterile; steam sterilized by end user prior to use	Supplied non-sterile; steam sterilized by end user prior to use	Supplied non-sterile; steam sterilized by end user prior to use	N/A	Supplied non-sterile; steam sterilized by end user prior to use	Supplied non-sterile; steam sterilized by end user prior to use	N/A	Supplied non-sterile; steam sterilized by end user prior to use	Supplied non-sterile; steam sterilized by end user prior to use	Same
Use	Single use	Single use	Single use	N/A	Single use	Single use	N/A	Single use	Single use	Same
Performance Testing										
Fatigue Testing	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	N/A	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	N/A	Fatigue testing according to ISO 14801	Fatigue testing according to ISO 14801	Same
Biocompatibility	Biocompatible according to ISO 10993-1:2018	Biocompatible according to ISO 10993-1:2018	Biocompatible according to ISO 10993-1:2018	N/A	Biocompatible according to ISO 10993-1:2018	Biocompatible according to ISO 10993-1:2018	N/A	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Same

x. Performance Testing Data

Non-clinical testing was performed on the Subject device SMARTbase Abutment System:

- Fatigue testing in accordance with ISO 14801 and the FDA Guidance Document entitled, "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" (May 12, 2004).
- Magnetic Resonance compatibility testing according to ASTM F2052, ASTM F2213, ASTM F2119 and ASTM F2182
- Verification of biocompatibility of the final device in accordance with ISO 10993-1
- Steam sterilization validation in accordance with ISO 17665-1
- Shipping validation in accordance with ASTM D4169
- Software verification and validation testing was provided for the subject abutment design library to demonstrate use with both the 3Shape Abutment Designer Software and ExocadAbutmentCAD software. Each software verification and validation testing was conducted to demonstrate that the restrictions prevent design of the top half component of the two-piece abutment outside of the allowable design limitations, including screenshots under user verification testing. In addition, the encrypted abutment design library was validated to demonstrate that the established design limitations and specifications are locked and cannot be modified within the abutment design library.

Clinical Performance Data:

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

xi. Conclusion

Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the SMARTbase Abutment System is deemed to be substantially equivalent to the Predicate Devices.