



October 10, 2019

Implant Direct Sybron Manufacturing LLC
% Yarmela Pavlovic
Partner
Hogan Lovells U.S. LLP
3 Embarcadero Center #1500
San Francisco, California 94111

Re: K191458

Trade/Device Name: Legacy™ SMARTBase Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: September 10, 2019
Received: September 10, 2019

Dear Yarmela Pavlovic:

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,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known)

K191458

Device Name

Legacy™ SMARTBase Abutments

Indications for Use (Describe)

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. 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 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 Legacy SMARTBase system consist of two major parts: the titanium base and zirconia top components make up a two-piece abutment.

- Legacy SMARTBase abutment for narrow (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: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.

Compatibility

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.

Implant Line	Body Diameter	Platform Diameter	Implant Length
Legacy1	3.7mm, 4.2mm, 4.7mm, 5.7mm	3.5mm, 4.5mm, 5.7mm	8mm, 10mm, 11.5mm, 13mm, 16mm
Legacy2, 3, 4, simplyLegacy2, simplyLegacy3	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	3.0mm, 3.5mm, 4.5mm, 5.7mm	

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

Implant Direct Sybron Manufacturing, LLC's Legacy SMARTBase Abutments

Submitter

Implant Direct Sybron Manufacturing LLC
3050 East Hillcrest Drive
Thousand Oaks, CA 91362

Phone: 818-444-3306

Contact Person: Reina Choi, Regulatory Affairs Manager

Date Prepared: October 9, 2019

Name of Device: Legacy™ SMARTBase Abutments

Classification Name: Endosseous Dental Implant Abutment (21 C.F.R. § 872.3630)

Regulatory Class: Class II

Primary Product Code: NHA

Secondary Product Code: PNP

Primary Predicate: Implant Direct Sybron Manufacturing, LLC's InterActive SMARTBase Abutments (K181359)

Reference Devices: Implant Direct Sybron Manufacturing, LLC's Spectra-System Dental Implants 2008 (K090234); 3Shape A/S's 3Shape Abutment Designer Software (K151455)

Device Description

The Legacy SMARTBase Abutment is a two-piece 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). The abutments are offered in three widths (narrow, regular, and wide), platform diameters of 3.0mm, 3.5mm, 4.5mm and 5.7mm, and collar (titanium base) heights of 0.25, 1.0, and 2.0 mm in order to accommodate different patient anatomies. The device is supplied with fixation screws that function as an extension of the implant to which the SMARTBase is secured, and is used with several accessories in conventional and digital workflows to fabricate the patient-specific restorations, including scan adapters, implant analogs, and off-axis tools.

The Legacy SMARTBase 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). The reference device, 3Shape

Abutment Designer Software (product code PNP), provides the digital design as an accessory to the physical dental abutment. The CAD design requires loading of the Implant Direct abutment design library via the 3Shape server to the 3Shape Software in order to design the zirconia top component within the established design limitations and specifications. The 3Shape software provides a digital design output file that is used for fabricating the finished device.

The digital workflow includes the following products (not subject devices to this submission):

- Ceramic material: Zenostar MT
- Cement: EMBRACE Wetbond Resin Cement (K071278)
- Intra-oral scanner: 3M Tru-Definition (K122467), ITero Scanner (K131101)
- Lab scanner: 3Shape D700 & 3Shape Scan-it Restoration Dental System (510(k) exempt, product code NOF)
- Abutment design software: 3Shape Abutment Designer™ Software (K151455)
- Milling machine: Wieland-Zenotec Select & Zenotec CAM

The device is single-use and supplied non-sterile, for sterilization by the end user. It is an externally-communicating device which comes in permanent contact (>30 days) with a patient’s tissue/bone.

Intended Use / Indications for Use

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. 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 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 Legacy SMARTbase system consist of two major parts: the titanium base and zirconia top components make up a two-piece abutment.

- Legacy SMARTBase abutment for narrow (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: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.

Compatibility

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.

Implant Line	Body Diameter	Platform Diameter	Implant Length
Legacy1	3.7mm, 4.2mm, 4.7mm, 5.7mm	3.5mm, 4.5mm, 5.7mm	8mm, 10mm, 11.5mm, 13mm, 16mm
Legacy2, 3, 4, simplyLegacy2, simplyLegacy3	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	3.0mm, 3.5mm, 4.5mm, 5.7mm	

The Legacy SMARTBase Abutments have the same intended use as the predicate InterActive SMARTBase Abutments, namely to aid in prosthetic rehabilitation by anchoring/supporting a restoration to a dental implant.

The Legacy SMARTBase Abutments also have similar indications for use as the predicate device and the differences do not alter the fundamental therapeutic/surgical use of the device because they either narrow its use as compared to the predicate or serve to clarify appropriate conditions of use. While the predicate device is more broadly indicated for use in both partially and fully edentulous patients, and accordingly can be used to support multi-unit restorations in addition to single-unit restorations, the target population/conditions to be treated with the Legacy SMARTBase Abutments are fully encompassed by those of the predicate device.

Additionally, the indications for use include reference to the lab scanners used with the SMARTBase Abutments. This component is also used with the previously cleared CAD/CAM system and was assessed in the previously performed CAD/CAM software verification and validation, which support both the primary predicate and the subject device. Therefore, the inclusion of the lab scanners is merely an editorial change for clarity and does not raise different questions of safety or effectiveness.

The other main difference between the two indications statements is that the predicate is compatible with the company's InterActive dental implant line as opposed to the Legacy implant line. This difference also does not raise different questions of safety or effectiveness when the device is used as labeled, because the same abutment compatibility with the company's Legacy implant line has previously been cleared in the reference device.

Summary of Technological Characteristics

Both the subject and predicate devices are based on the fundamental principle of providing support for dental implants in order to enable a dental restoration to be inserted into the patient's mouth and rehabilitate a patient's chewing function. At a high level, the subject and predicate devices are based on the following same technological elements:

- Both are two-piece abutments comprised of a Titanium base and a zirconia top which can be modified to patient-specific requirements.
- Both are used in the conventional and digital workflows, with similar auxiliary devices, to facilitate fabrication of a patient-specific dental restoration.
- Both feature the same fundamental design (e.g., size and diameter ranges, post height).

The main technological difference between the subject and predicate devices is the abutment- implant interface: The subject device mates with the Legacy implant line whereas the predicate device mates with the InterActive implant line.

A table comparing the key features of the subject and predicate devices is provided below.

Performance Data

Non-clinical testing was performed on the proposed device, including mechanical strength (fatigue), biocompatibility, cleaning and steam sterilization validation, and software verification/validation. Successful test results indicated that the Legacy SMARTBase Abutments will perform as intended, and support the device's substantial equivalence.

- Dynamic Fatigue testing on the worst-case device configurations per ISO 14801:2016 (consistent with, FDA's *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*). Results confirmed that the Legacy SMARTBase abutments perform equivalently to the predicate device.

- Biocompatibility evaluation was conducted according to ISO 10993-1 and FDA's corresponding June 2016 guidance, for an externally-communicating device with permanent (>30 day) contact with patient bone/tissue/blood. Testing was performed in accordance with the following standards: ISO 10993-2, ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12 and ISO 10993-33 to demonstrate that the devices met biocompatibility requirements for its intended use.
- The proposed devices are provided non-sterile and intended to be steam sterilized by the end user. Steam sterilization validation according to ISO 14947 and ISO 17665-1 to demonstrate attainment of a sterility assurance level of 10^{-6} using the same steam sterilization processes as the predicate device.
- Software validation ensured the ability of the system to scan the articulator and design the model to configure to the user's need to successfully create abutments employing 3Shape software within established design limitations and specifications. Verification and validation testing performed in support of the previously cleared InterActive SMARTBase Abutments (K181359) was also relied upon as the subject device employs the identical off-the-shelf abutment designer software and milling unit.

Clinical data is not needed to characterize performance and establish substantial equivalence. The non-clinical test data characterize all performance aspects of the device based on well-established scientific and engineering principles. Thus, clinical testing has not been conducted on this product.

Conclusion

The Legacy SMARTBase Abutments have the same intended use and principles of operation, and similar indications for use and technological characteristics, as its predicate device. The minor differences in indications do not alter the intended therapeutic/surgical use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the Legacy SMARTBase Abutment system and its predicate device raise no new issues of safety or effectiveness, and have been further addressed by performance data which demonstrates that the device performs in a substantially equivalent manner as the predicate device. Thus, the Legacy SMARTBase Abutments are substantially equivalent to the predicate InterActive SMARTBase Abutment System (K181359).

Substantial Equivalence Table

	Legacy SMARTBase Abutment (Subject Device)	InterActive SMARTBase Abutment (K181359) (Primary Predicate)	Spectra-System Dental Implants 2008 (K090234) (Reference Device)	3Shape Software (K151455) (Reference Device)
Intended Use / Indications for Use	<p>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. Legacy SMARTBase engaging abutments are intended for use in the mandible or maxilla in support of single unit restorations.</p> <p>The Legacy 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 Legacy SMARTBase system consist of two major parts: the titanium base and zirconia top components make up a two-piece abutment.</p> <ul style="list-style-type: none"> • Legacy SMARTBase abutment for narrow (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: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors. 	<p>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 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.</p> <p>Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.</p> <ul style="list-style-type: none"> • 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. 	<p>Spectra-System Dental Implants 2008 are comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single tooth or multiple- tooth restorations, recognizing bone stability and appropriate occlusal load requirements.</p>	<p>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 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.</p>
Compatibility	<ul style="list-style-type: none"> • Implant Direct Legacy1: body diameter 3.7 – 5.7mm, platform diameter 3.5, 4.5, 5.7mm 3.5, 4.5, 5.7mm; 	<ul style="list-style-type: none"> • Implant Direct interactive (3.2, 3.7, .3, 5.0mm body diameter, 3.0 and 3.4mm) • Implant Direct SwishActive 	N/A	N/A

	Legacy SMARTBase Abutment (Subject Device)	InterActive SMARTBase Abutment (K181359) (Primary Predicate)	Spectra-System Dental Implants 2008 (K090234) (Reference Device)	3Shape Software (K151455) (Reference Device)
	<ul style="list-style-type: none"> Implant Direct Legacy2, 3, 4, simplyLegacy2 & 3: body diameter 3.2 – 7.0mm; platform diameter 3.0, 3.5, 4.5, 5.7mm, excluding 6mm length 	(3.3, 4.1, 4.8mm body diameter, 3.0 and 3.4mm platform)		
Prosthesis Attachment	Screw- or cement-retained		Screw- or cement-retained	N/A
Restoration	Single-unit	Single-unit and multi-unit	Single-unit and multi-unit	Single-unit and multi-unit
Abutment Angulation	0° to 30°	0° to 30°	0° to 30°	N/A
Abutment Collar Heights	0.25mm - 2mm	1.0mm – 2.0mm	1.0mm – 3.0mm	N/A
Post Height	4mm minimum		N/A	N/A
Abutment material and surface treatment	Titanium & Zirconia; abutments are titanium and anodized gold and pink (with grooves machined for cement adhesion)		Titanium alloy	N/A
Cement Adhesive	EMBRACE (K071278)		N/A	N/A
Screw Material	Titanium		Titanium	N/A
Implant Interface Platform	3.0mm, 3.5mm, 4.5mm, and 5.7mm platform diameter	3.0mm and 3.4mm platform diameter	3.0, 3.5, 4.5, and 5.7mm diameter at the interface	N/A
Sterility	Supplied non-sterile; steam sterilized by end user prior to use		Supplied non-sterile; steam sterilized by end user prior to use	N/A
Number of uses	Single use		Single use	N/A