May 8, 2020

Implant Direct Sybron Manufacturing, LLC
% Kelliann Payne
Partner
Hogan Lovells U.S. LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K192218
Trade/Device Name: Custom Legacy and Custom InterActive Titanium Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA
Dated: April 10, 2020
Received: April 10, 2020

Dear Kelliann Payne:

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.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*
K192218

Device Name

Custom Legacy and Custom InterActive Titanium Abutments

Custom Titanium Abutments are customizable devices intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients.

- Custom Titanium Abutment for narrow (3.2mmD, 3.3mmD) implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements.
- Custom Titanium Abutment for short (8mm) 3.7mmD implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.

Custom Legacy Titanium Abutments are compatible at the implant-level with Legacy1, Legacy2, Legacy3, Legacy4, simplyLegacy2 and simplyLegacy3 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 to 16mm
Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	3.0mm, 3.5mm, 4.5mm, 5.7mm	

Custom InterActive Titanium Abutments are compatible at the implant-level with InterActive, SimplyInterActive and SwishActive implants, excluding 6mm length implants.

Implant Line	**Body Diameter**	**Platform Diameter**	**Implant Length**
InterActive, simplyInterActive	3.2mm, 3.7mm, 4.3mm, 5.0mm	3.0mm, 3.4mm	8mm to16mm
SwishActive	3.3mm, 4.1mm, 4.8mm	3.0mm, 3.4mm	8mm to16mm

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.

510(k) SUMMARY
Implant Direct Sybron Manufacturing, LLC's
Custom Legacy Titanium Abutments and Custom InterActive Titanium Abutments

Submitter: Implant Direct Sybron Manufacturing, LLC
Address: 3050 East Hillcrest Drive
Thousand Oaks, CA 91362
Phone: (818) 444-3306
Contact Person: Reina Choi, Regulatory Affairs Manager

Date Prepared: May 7, 2020

Name of Device: Custom Legacy and Custom InterActive Titanium Abutments
Common or Usual Name: Endosseous dental implant abutments
Regulation Number: 21 C.F.R. § 872.3630
Classification Panel: Dental
Regulatory Class: Class II
Product Code: NHA

Predicate Device: Implant Direct Sybron Manufacturing, LLC's Legacy Abutment System (K060063)

Reference Devices:

Implant Direct Sybron Manufacturing, LLC's InterActive/SwishPlus2 Implant System (K130572)
3Shape A/S's 3Shape Abutment Designer Software (K151455)
Implant Direct Sybron Manufacturing, LLC's InterActive SMARTBase Abutments (K181359)

Device Description

The Custom Legacy Titanium Abutments and Custom InterActive Titanium Abutments (collectively the "Custom Titanium Abutments") are one-piece hex type engaging abutments comprised of Titanium 6AL-4V ELI, which serve as a final abutment upon which a prosthetic dental restoration will be fitted.

The Custom Legacy Abutments are offered in 3.0mm, 3.5mm, 4.5mm, and 5.7mm diameters that correspond to the platform diameters of the Legacy Implant System; the Custom InterActive Abutments are offered in 3.0mm and 3.4mm diameters that correspond to the InterActive Implant System. The devices are supplied with fixation screws that are placed through the abutment to secure it to the implant's reciprocal hex platform. The Custom Abutments are provided with a large amount of modifiable material to accommodate the digital workflow used for device customization. Customization of the final abutment is performed in Implant Direct's Custom Direct laboratory under Implant Direct's manufacturing control, where the devices are milled to meet individual patient specifications. The digital workflow uses the following additional devices:

- 3Shape Abutment Design Software (K151455)
    - Dental System Control Panel
    - Dental Designer
- Lab Scanner (3Shape D700 and 3Shape Scan-it Restoration Dental System (510(k)-exempt, Product Code NOF)
- Intra-oral scanners
    - 3M True Definition Scanner (K122467)
    - Itero Scanner Software (K131101)

The Custom Abutments are patient-specific and may be modified within the following parameters:

- Maximum angle of 30° from the axis of the implant
- Minimum wall thickness of 0.4mm
- Minimum post height of 4mm

The Custom Abutments are available using either a Design-and-Mill or Mill-only digital workflow. With the Design-and-Mill process flow, the patient's dentition information (impression or intraoral scan) is sent to Implant Direct. Implant Direct will design an abutment and forward the design to the end user for approval prior to manufacturing. With the Mill-only process flow, the end user uses intra-oral scanners and lab scanners to design the abutment using the 3Shape software. The abutment design file (.stl) is sent to Implant Direct for manufacturing.

The Custom Abutments are single-use and supplied non-sterile, for sterilization by the end user. They are externally-communicating devices which come in permanent contact (>30 days) with a patient's tissue/bone.

Intended Use / Indications for Use

Custom Titanium Abutments are customizable devices intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients.

- Custom Titanium Abutment for narrow (3.2mmD, 3.3mmD) implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements.
- Custom Titanium Abutment for short (8mm) 3.7mmD implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.

Custom Legacy Titanium Abutments are compatible at the implant-level with Legacy1, Legacy2, Legacy3, Legacy4, simplyLegacy2 and simplyLegacy3 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 to 16mm
Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	3.0mm, 3.5mm, 4.5mm, 5.7mm	

Custom InterActive Titanium Abutments are compatible at the implant-level with InterActive, SimplyInterActive and SwishActive implants, excluding 6mm length implants.

Implant Line	**Body Diameter**	**Platform Diameter**	**Implant Length**
InterActive, simplyInterActive	3.2mm, 3.7mm, 4.3mm, 5.0mm	3.0mm, 3.4mm	8mm to16mm
SwishActive	3.3mm, 4.1mm, 4.8mm	3.0mm, 3.4mm	8mm to16mm

The minor differences in indications for use of the Custom Abutments as compared to the predicate device do not alter the intended therapeutic effect of these devices or raise different questions of safety or effectiveness, as they are primarily intended for clarification of the appropriate conditions of use (*e.g.,* compatibility) and to facilitate achievement of the same general intended use (in

conjunction with dental implants to support crowns and bridges for edentulous or partially edentulous patients) via a digital dentistry workflow.

Summary of Technological Characteristics

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

- Both subject devices and the predicate are one-piece abutments comprised of Titanium 6AL-4V ELI which can be modified to patient-specific requirements.
- Both subject devices and the predicate utilize a hex engaging feature that attaches to the reciprocal hex platform of the corresponding implant.
- Both subject devices and the predicate feature the same fundamental design (e.g., straight post for modifying custom features) and same corresponding screw size.

The Custom Abutments are available using either a Design-and-mill or Mill-only digital workflow, both of which employ the scanners identified in the Device Description section above and the 3Shape Abutment Designer Software (K151455).

- The Design-and-mill workflow uses impression or intraoral scan data provided by the dental practitioner as input for Implant Direct to design a Custom Abutment using 3Shape within its controlled facility. The resulting abutment design is approved by the dental practitioner and manufactured within the Implant Direct facility.
- The Mill-only workflow allows the dental practitioner or dental laboratory staff to design the Custom Abutment using the 3Shape software. An encrypted .stl file is then transmitted to Implant Direct for manufacturing. A digital library provided by Implant Direct controls the abutment design parameters.

Thus, the main technological difference between the subject and predicate devices is the use of a digital workflow to modify the stock material of the subject devices into a final abutment, as compared to the conventional workflow used to modify/finalize the predicate abutment. This difference does not raise different questions of safety or effectiveness, because all of the devices are modified to clinician-prescribed, patient-specific parameters, and the same considerations apply around the safety and integrity of the final product under the anticipated loads in the mouth. In all cases with both the predicate and reference devices, as well as with the subject devices using either the Design-and-Mill or Mill-only workflows, the end user must approve the final abutment parameters/design. Moreover, the off-the-shelf software used to fabricate the Custom Abutments has been previously cleared by FDA (K151455) for use in producing abutments. The Custom InterActive Abutment has a slightly different connection to the implant than the predicate, but this connection supports the same functionality (mating between implant and abutment) and was previously cleared by FDA in the InterActive implant reference device (K130572).

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

Performance Data

Non-clinical testing was performed on the subject device to support its safety and performance. Successful test results indicate that the Custom Titanium Abutments will perform as intended and

support the device's substantial equivalence, as summarized below.

Biocompatibility

The Custom Abutments were subjected to biocompatibility testing according to ISO 10993-1. Worst-case Custom Abutments were tested for Cytotoxicity (ISO 10993-5), Sensitization (ISO 10993-10), Irritation (ISO 10993-10), Systemic toxicity (ISO 10993-11), and Mutagenicity (ISO 10993-3). The testing showed no adverse biological effects.

Fatigue Testing

Fatigue testing was performed per ISO 14801. Testing was performed on worst-case scenario designs and implant-abutment loading configurations. The design parameters considered were maximum angulation (30 degrees), minimum wall thickness (0.4mm), minimum post height (4mm), and maximum overall length of abutment.

Steam Sterilization

Steam sterilization validation was performed per ISO 17665 on worst-case Custom Abutments, taking into consideration overall size, surface area, weight, and lumen diameter. The validation ensures an SAL of 10^{-6}.

Software Verification and Validation

Software verification and validation testing was performed for the off-the-shelf abutment design library used in the subject devices' digital workflow, 3Shape Abutment Designer™ Software (K151455). The testing demonstrated that the established design limitations and specifications are locked and cannot be modified by the end user within the abutment design library.

No animal or clinical testing was submitted in support of this 510(k) notice.

Conclusion

The Custom Legacy and Custom InterActive Titanium Abutments are as safe and effective as the predicate Legacy Abutment System (K060063). The Custom Titanium Abutments and previously cleared Legacy Scalloped (now called Straight Contoured) Abutment have the same intended use and very similar indications, technological characteristics, and principles of operation. The minor differences between the subject and predicate devices do not alter the therapeutic/surgical use of the device and do not present different questions of safety or effectiveness, because they do not represent fundamental differences in design or mechanism of action. In addition, performance data demonstrates that the subject Custom Abutments are as safe and effective as the predicate device. Thus, the Custom Titanium Abutments are substantially equivalent to the Legacy Abutment System.

Substantial Equivalence Table

	Custom Titanium Abutments (Subject Device)	Legacy Abutment System (K060063) (Predicate Device)	InterActive SwishPlus2 Implant System (K130572) (Abutment Component: Reference Device)	3Shape Abutment Designer Software (K151455) (Reference Device)
Classification	21 CFR § 872.3630; Product Code NHA		21 CFR §§ 872.3640, 872.3630; Product Codes DZE, NHA	21 CFR § 872.3630; Product Code PNP
Intended Use / Indications for Use	Custom Titanium Abutments are customizable devices intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients. • Custom Titanium Abutment for narrow (3.2mmD, 3.3.mD) implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements. • Custom Titanium Abutment for short (8mm) 3.7mmD implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.	The Legacy Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients.	The InterActive/SwishPlus2 Implant System consists of two-piece implants for one-stage or two-stage surgical procedures. The abutment component of the system is included herein as a reference device. 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 abutment support for fixed bridgework: Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. 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.	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.
Compatibility	Custom Legacy Titanium Abutments are compatible at the implant-level with Legacy1, Legacy2, Legacy3, Legacy4, simplyLegacy2 and simplyLegacy3 implants, excluding 6mm length implants. Custom InterActive Titanium Abutments are compatible at the implant-level with InterActive, SimplyInterActive and SwishActive implants, excluding 6mm length implants.	The Legacy Abutment System is compatible with implants that have mating diameters, lead-in bevels, internal hex sizes, and 1-72UNF internal threads, as shown in the Zimmer Dental Tapered Screw-Vent Surgical Manual. Implant Direct LLC will monitor the compatible implants for modifications to ensure future compatibility. In the event of any modification, Implant Direct LLC will either modify the Legacy abutment to ensure compatibility, or cease	InterActive and SwishPlus2 implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive NP (Narrow Platform - 3.0mm diameter) and NobelActive RP (Regular Platform - 3.4mm diameter) abutments. InterActive 3.0 and 3.4mm abutments are prosthetically compatible with Nobel Biocare conical connection. NobelActive NP (Narrow Platform- 3.0mm diameter) and NobelActive RP (Regular Platform - 3.4mm diameter) (3.5-5.0mmD, 8.5-18mmLength) implants.	N/A

	Custom Titanium Abutments (Subject Device)	Legacy Abutment System (K060063) (Predicate Device)	InterActive SwishPlus2 Implant System (K130572) (Abutment Component: Reference Device)	3Shape Abutment Designer Software (K151455) (Reference Device)
		claiming compatibility to the modified Zimmer Dental Screw-Vent implants.		
Material	Titanium 6AL-4V ELI			N/A
General Design	One-piece abutment with hex engaging feature and straight post for modifying custom features			N/A – Software only device
Implant/Abutment Interface	Internal hex (Legacy) and Internal hex with 12 degree conical lead-in bevel (InterActive)	Internal hex with 45 degree bevel	Internal hex with 12 degree conical lead-in bevel	N/A – Software only device
Implant/Abutment Interface Diameters	Legacy Model: 3.0mmD, 3.5mmD, 4.5mmD, 5.7mmD InterActive Model: 3.0mmD, 3.4mmD	3.5mmD, 4.5mmD, 5.7mmD	3.0mmD, 3.4mmD	N/A – Software only device
Cuff Diameters	3.2mm – 12.7mm	4.5mm, 5.4mm, 6.5mm	3.7mm, 4.7mm, 5.7mm	N/A – Software only device
Modifying Workflow	Customization design provided by customer or prepared in-house and then machined in-house	Abutments are modified by outside laboratory and/or chairside by the dentist using hand instruments.		N/A
Screw Material and Thread	Titanium alloy; M1.6, M2, 1-72UNF	Titanium alloy; 1-72 UNF	Titanium alloy; M1.6, M2	N/A
Single vs. Multiple Use	Single-use	Single-use	Single-use	Multiple use
Packaging	Packaged affixed via a fixation screw to a plastic screw-mount. The screw-mount is placed within a larger outer vial and closed with a vial cap.			N/A – Software only device
Sterilization	Sold non-sterile, Steam sterilization by end user		Sold non-sterile. Steam sterilization by end user after abutment modification and prior to use.	Non-sterile