August 15, 2018

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

Re: K181359
Trade/Device Name: InterActive SMARTBase Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: May 18, 2018
Received: May 22, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K181359

Device Name

InterActive SMARTBase Abutments

Indications for Use *(Describe)*

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.

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.

Compatibility:

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.

Manufacturer	Implant Line	Body Diameter	Implant Platform
Implant Direct	InterActive	3.2mm, 3.7mm, 4.3mm, 5.0mm	3.0mm, 3.4mm
Implant Direct	SwishActive	3.3mm, 4.1mm, 4.8mm	3.0mm, 3.4mm

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.

IMPLANT DIRECT™
3050 E. Hillcrest Drive
Thousand Oaks, CA 91362 USA

K181359

510(k) SUMMARY

1. SUBMITTER

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

Date Prepared: August 3, 2018

Contact Person: Reina Choi
Senior Regulatory Affairs Specialist
818-444-3306
reina.choi@implantdirect.com

2. DEVICE NAME

Proprietary Name:	InterActive SMARTBase Abutments
Classification Name:	Endosseous Dental Implant Abutment (21 CFR 872.3630)
Primary Product Code:	NHA
Secondary Product Code:	PNP

3. PREDICATE DEVICE(S)
   - InterActive/SwishActive Implant System (K143011) – Primary Predicate
   - InterActive/SwishPlus2 Implant System (K130572) – Reference Device
   - Sirona Dental CAD/CAM System (K111421) – Reference Device
   - 3Shape Abutment Designer™ Software (K151455) – Reference Device

4. DEVICE DESCRIPTION

The InterActive SMARTBase abutments system is a line extension of the previously cleared Implant Direct device, 2014 InterActive/SwishActive Implant System. The InterActive SMARTBase abutments are comprised of engaging abutments, non-engaging abutments, modified zirconia engaging abutments, modified zirconia non-engaging multi-unit bridges, and fixation screws that are intended to function as an extension of the implant. The proposed SMARTBase Abutment is a two-piece abutment consisting of titanium base and zirconia top components. To fabricate the zirconia top component that fits the titanium base, there are three workflow options: (1) using a press-ceramic material that is formed by conventional wax-up technique by the end user, (2) the zirconia top component is designed and milled by Implant Direct in stock sizes and provided to the end user to be placed on the titanium base for forming two-piece abutment, and (3) digital workflow using 3Shape where CAD design and milling of the zirconia top component is done at the end user's dental laboratory/office to be placed on the titanium base. The CAD design requires loading of Implant Direct abutment design library to the 3Shape Software to design the zirconia top component within the established design limitations and specifications. The digital workflow includes the use of the following products (note that these are not subject devices to this submission):

- Ceramic material: Zenostar MT
- Cement: EMBRACE Wetbond Resin Cement
- Intra oral scanners: 3M Tru-Definition, ITero Scanner
- Abutment design software: 3Shape Abutment Designer™ Software (K151455)
- Milling machine: Wieland-Zenotec Select & Zenotec CAM

TABLE 1. Product Specifications

Type	Material	Implant Platform/ Connection Hex	Abutment Diameter/ Cuff Heights	Post Heights	Angulation
Engaging Abutments	Titanium Alloy/ Zirconia	3.0mmD/2.2mm 3.4mmD/2.6mm	4.9mm Minimum/ 1mm & 2mm	4mm Minimum	0° to 30°
Non-engaging Abutments	Titanium Alloy/ Zirconia	3.0mmD 3.4mmD	5.7mm Minimum/ 1mm & 2mm	4mm Minimum	0° to 30°
Standard Straight and Angled Zirconia engaging Abutments	Titanium Alloy/ Zirconia	3.0mmD/2.2mm 3.4mmD/2.6mm	4.9 mm Minimum/ 1mm & 2mm	4mm Minimum	0°, 8°, 15°
Modified Zirconia engaging	Titanium Alloy/ Zirconia	3.0mmD/2.2mm 3.4mmD/2.6mm	4.9mm Minimum/ 1mm & 2mm	4mm Minimum	0° to 30°

Abutments					
Modified zirconia non-engaging multi-unit bridges	Titanium Alloy/ Zirconia	3.0mmD 3.4mmD	5.7mm Minimum/ 1mm & 2mm	N/A	0 to 30°
Fixation Screws	Titanium Alloy	3.0mmD 3.4mmD	N/A	N/A	N/A

TABLE 2. Compatible Implants with Proposed InterActive SMARTBase Abutments

Implant Brand (Manufacturer)	510(k) #	Model
Implant Direct Sybron Manufacturing, LLC	K143011 K130572	InterActive Implant System and SwishActive Implant System (Conical connection)

5. INDICATIONS FOR USE

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.

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.

Compatibility:
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.

Manufacturer	Implant Line	Body Diameter	Implant Platform

Implant Direct	InterActive	3.2mm, 3.7mm, 4.3mm, 5.0mm	3.0mm, 3.4mm
Implant Direct	SwishActive	3.3mm, 4.1mm, 4.8mm	3.0mm, 3.4mm

6. TECHNOLOGICAL CHARACTERISTICS COMPARISON

Technological Characteristics	**Proposed Device: InterActive SMARTBase Abutments (K181359)**	**Primary Predicate: InterActive Engaging Abutments(K143011)**	**Reference Device: InterActive Non-Engaging Abutments (K130572)**	**Reference Device: Sirona Dental CAD/CAM-System (K111421)**	**Reference Device: 3Shape Abutment Designer™ Software (K151455)**
Manufacturer	Implant Direct Sybron Manufacturing, LLC	Implant Direct Sybron Manufacturing, LLC	Implant Direct Sybron Manufacturing, LLC	Dentsply - Sirona	3Shape
Indications for Use	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 abutment 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	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 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. These implants are also indicated for multiple tooth replacements or denture stabilization.	InterActive/SwishPlus2 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 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 Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. The system consists of three major parts: TiBase, InCoris mesostructure, and CAD/CAM software. Specifically, the InCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The InCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the InCoris mesostructure.	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.

Technological Characteristics	Proposed Device: InterActive SMARTBase Abutments (K181359)	Primary Predicate: InterActive Engaging Abutments(K143011)	Reference Device: InterActive Non-Engaging Abutments (K130572)	Reference Device: Sirona Dental CAD/CAM-System (K111421)	Reference Device: 3Shape Abutment Designer™ Software (K151455)
	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.				
Compatibility	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 and SwishActive 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.	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.	The InCoris mesostructure and TiBase two-piece abutment is compatible with the following implant systems: Nobel Biocare Replace (K020646), Nobel Biocare Branemark (K022562), Friadent Xive (K013867), Biomet 3i Osseotite (K980549), Astra Tech Osseospeed (K091239), Zimmer Tapered Screw-Vent (K061410), Straumann Synocta (K061176), Straumann Bone Level (K053088), Biomet 3i Certain (K014235), Nobel Biocare Active (K071370).	N/A

Technological Characteristics	Proposed Device: InterActive SMARTBase Abutments (K181359)	Primary Predicate: InterActive Engaging Abutments(K143011)	Reference Device: InterActive Non-Engaging Abutments (K130572)	Reference Device: Sirona Dental CAD/CAM-System (K111421)	Reference Device: 3Shape Abutment Designer™ Software (K151455)
General Design	Abutment body consisting of a titanium base and supplied with a fixation screw. The bases are provided with straight, angled, and modified zirconia tops for patient specific devices. The devices are also provided without a zirconia top and a superstructure or hybrid crown or bridge can be milled to fit the bases intended to be manufactured at Implant Direct Manufacturing facility.	Abutment body consisting of a titanium base and supplied with a fixation screw. The bases are provided with straight, angled, or a modified top intended to be manufactured at Implant Direct Manufacturing facility.	Abutment body consisting of a titanium base and supplied with a fixation screw. The bases are provided without a restoration.	The TiBase is a premanufactured prosthetic component directly connected to endosseous dental implants with a screw and is intended for use as an aid in prosthetic rehabilitation.	N/A
Abutment Angle	0^0 to 30^0	0^0 to 30^0	0^0 to 30^0	0^0 to 20^0	N/A
Restoration	Single Unit, Multi-Unit	Single Unit, Multi-Unit	Multi-Unit	Single Unit, Multi-Unit	N/A
Post Height	Single Unit - Minimum 4 mm Multi-Unit - Minimum 4 mm	Single Unit - Minimum 4 mm Multi-Unit - Minimum 4 mm	Minimum of 4mm height required	Minimum 4mm	N/A
Anti-Rotation Feature	Single Unit - One Flat Multi-Unit - One Flat	Single Unit - Three Vertical Grooves at 120° Multi-Unit - One Anti-Rotation Key	Multi-Unit - One Flat	Single anti-rotation feature	N/A
Prosthesis Attachment	Screw Retained	Screw or Cement Retained	Acrylic	Screw or Cement Retained	N/A
Screw Thread	M1.6, M2	M1.6, M2	M1.6, M2	M1.6, M2 (NobelActive)	N/A

Technological Characteristics	Proposed Device: InterActive SMARTBase Abutments (K181359)	Primary Predicate: InterActive Engaging Abutments(K143011)	Reference Device: InterActive Non-Engaging Abutments (K130572)	Reference Device: Sirona Dental CAD/CAM-System (K111421)	Reference Device: 3Shape Abutment Designer™ Software (K151455)
Interface Platform	3.0mm and 3.4mm Platform	3.0mm and 3.4mm Platform	3.0mm and 3.4mm Platform	NobelActive, NP and RP	N/A
Interface Connection	Engaging and Non-Engaging Internal Hex Conical connection	Engaging and Non-Engaging Internal Hex Conical connection	Non-Engaging	Engaging and Non-Engaging Internal Hex Conical connection	N/A
Implant Compatibility	InterActive 3.0mm and 3.4mm	InterActive 3.0mm and 3.4mm and NobelActive NP and RP	InterActive 3.0mm and 3.4mm and NobelActive NP and RP	NobelActive NP and RP	N/A
Abutment Material	Titanium & Zirconia	Titanium & Zirconia	Titanium	Tibase - Titanium 6AL4V, Cercon HT	N/A
Abutment Surface Treatment	Abutments are titanium anodized gold and pink (grooves are machined for cement adhesion).	Abutments are anodized gold (grooves are machined for cement adhesion).	None. (grooves are machined for acrylic adhesion)	Cemented surfaces are blasted with aluminum oxide.	N/A
Cement (Adhesive)	EMBRACE	EMBRACE	Acrylic	Panavia F2.0	N/A
Screw Material	Titanium	Titanium	Titanium	Titanium	N/A
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Non-Sterile	N/A
Sterilization Method	Steam Sterilization	Steam Sterilization	Steam Sterilization	Steam Sterilization	N/A
Use	Single-Use	Single-Use	Single-Use	Single-Use	N/A

Technological Characteristics	Proposed Device: InterActive SMARTBase Abutments (K181359)	Primary Predicate: InterActive Engaging Abutments(K143011)	Reference Device: InterActive Non-Engaging Abutments (K130572)	Reference Device: Sirona Dental CAD/CAM-System (K111421)	Reference Device: 3Shape Abutment Designer™ Software (K151455)
Packaging	Inside a vial sealed with a cap	Inside a vial sealed with a cap	Inside a vial sealed with a cap	Unknown	N/A

The proposed device has the same intended use and similar technological characteristics to that of the predicate device and reference devices. The proposed SMARTBase devices are different from the primary predicate devices, K143011, by 1) having a different titanium anodize color, 2) having a different anti-rotation feature for the zirconia top, 3) using a digital workflow, and 4) having a minimum zirconia wall thickness that is 0.2mm larger. The proposed devices are different from the reference devices (K130572 and K111421) by 1) having a titanium anodize color, 2) having a different anti-rotation feature for the zirconia top, and 3) having a different cement.

The anodize process used for the proposed SMARTBase is the same as the primary predicate devices (K143011). The reference devices (K130572) are not processed through a titanium anodize procedure. The proposed titanium anodizing colors only changes the oxide layer thickness. The thickness of the oxide layer determines the color of the device. The anti-rotation feature is used to orient the zirconia top to the correct position. The anti-rotation feature in the SMARTBase is a flat rather than three vertical grooves as in the primary predicate device. The reference device (K130572) has the same type of anti-rotation feature as the proposed device. The reference device (K111421) has a machined titanium key that fits into an internal keyway in the zirconia to prevent rotation. The proposed device uses different cement for attachment from those used in the references devices. The proposed device uses 3Shape Abutment Designer Software, while the reference device (K111421) uses Sirona Dental CAD/CAM Software. Both software (3Shape and Sirona Dental CAD/CAM Software) provide a digital design output file that is used for fabricating the finished device. The proposed devices include the two-piece abutments as a physical output as well as a validated manufacture process. The reference device 3Shape Abutment Designer Software does not provide any physical parts that come into contact with patient and only provides the digital design as an accessory to the physical dental abutment system. The differences in the indications for use of the proposed device and the reference device (3Shape Abutment Designer Software) are related to a lack of a physical output from the reference device.

Overall, any noted differences have been evaluated and supported by non-clinical testing and therefore do not affect substantial equivalence.

7. NON-CLINICAL TESTING

Non-clinical testing was performed on the proposed device. Testing include mechanical strength, biocompatibility, cleaning and steam sterilization validation, and software verification & validation. Successful test results indicated that the subject device will perform as intended and support the substantial equivalence of the InterActive SMARTBase abutments.

- Mechanical testing

- Fatigue testing was performed on worst-case configuration of proposed devices per ISO 14801. Results indicated that the proposed SMARTBase abutments successfully completed endurance testing and was equivalent to the predicate devices.
- Screw Torque testing was performed on worst case drivers. Results indicated the drivers met the specified torque as the predicate device.

- Biocompatibility testing
  - Biological evaluation was conducted according to ISO 10993-1. Cytotoxicity testing per ISO 10993-5 was conducted on the finished devices. Results indicate that the devices met biocompatibility requirements for its intended use.

- Software Verification & Validation

  Software verification and validation testing was provided for the subject abutment design library to demonstrate use with 3Shape Abutment Designer™ Software (K151455). Software verification and validation testing was conducted to demonstrate that the restrictions prevent design of the zirconia top component outside of 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.

- Steam Sterilization Validation
  - The proposed devices are provided non-sterile and intended to be steam sterilized by the end user. Steam sterilization validation was performed on the primary predicate device per ISO 17665-1 and ISO 17665-2. The proposed devices have the same materials, same manufacturing processes, and same sterilization parameters as the predicate devices. The proposed devices are expected to meet the same sterilization requirements and thus no additional testing is needed.

8. CLINICAL TESTING

Clinical performance testing has not been performed. Clinical testing is not needed to support substantial equivalence.

9. CONCLUSION

The intended use, the indications for use, and technological characteristics of the proposed devices are similar to those of the predicate devices. Any noted differences between the proposed and predicate devices do not affect the intended use and have been addressed by the performance data. Based on the intended use, technological characteristics, and

applicable performance data included in this submission, the proposed devices have been shown to be substantially equivalent to the predicate devices.