DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 24, 2017

Re: K162633
Trade/Device Name: Custom Bars
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 26, 2017
Received: June 27, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

for
Lori Wiggins
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162633

Device Name

Custom Bars

Indications for Use *(Describe)*

Implant Direct Custom Bars are patient specific devices indicated for attachment to dental implants in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function.

Custom bars are compatible at the implant level with InterActive (3.4mm Platform) & SwishActive (3.4 Platform) System implants.

Manufacturer	Implant Line	Body Diameter	Implant Platform
Implant Direct	InterActive	4.3mm, 5.0mm	3.4mm
Implant Direct	SwishActive	4.8mm	3.4mm

Custom bars are compatible at the abutment level with InterActive (3.4mm Platform) & SwishActive (3.4 Platform) system straight multi-unit abutments.

Manufacturer	Implant Line	Implant Platform
Implant Direct	InterActive	3.4mm
Implant Direct	SwishActive	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.

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K162633

SECTION 5. 510(k) SUMMARY

1. SUBMITTER

Implant Direct Sybron Manufacturing LLC
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Date Prepared: July 21, 2017

2. DEVICE

- Proprietary Name: Custom Bars
- Classification Name: Endosseous Dental Implant Abutment
- CFR: 21 CFR 872.3630
- Regulatory Class: II
- Product Code: NHA

3. PREDICATE DEVICES

- Dentsply International ISUS Implant Suprastructures (K122424) – Primary Predicate
- Nobel Biocare NobelProcera Overdenture Bar (K132749) – Reference
- Biomet 3i CAM StructSURE Overdenture Bars (K101582) – Reference

4. DEVICE DESCRIPTION

Implant Direct Custom Bars are computer-aided design/computer-aided manufacturing, individually designed prosthetic devices for partially or fully edentulous restorations. The bars and fixation screws are made from Wrought Titanium Alloy conforming to an FDA recognized consensus standard ASTM F136. The Custom Bars consist of two

device types: fixed-detachable frameworks and overdenture bars. The bar systems consists of the bars as well as fixation screws to facilitate the attachment to the dental implants.

Implant Direct Custom Bars are attached directly to an implant to provide support for the fabricated denture. The implant specific interfaces on the Custom Bars are designed and manufactured with precise mating features in order to seat to the mating surfaces of the implants or abutments.

The Implant Direct Custom Bars are designed and produced at Implant Direct under the direction of clinical professionals. The patient requirements and implant locations are obtained conventionally or digitally and a bar is designed, using CAD software, according to established customization parameters. Once the design is finished, the bar design is sent to the clinician for approval before manufacture. After bar design approval is received, the bar design is milled using a precise CAM system, inspected, cleaned, packaged non-sterile, and shipped to the customer where it is finished into the final restoration.

Customization Parameters

Parameter	Minimum	Maximum
Number of Cylinders	4 **Note 1**	10
Bar Span	0mm	17mm
Distal cantilever extension **Note 2**	0mm	10mm
Superstructure Cylinder divergence	0°	40° divergence between two implants with no more than 20° angulation for any one implant.
Cylinder height	0mm	7mm
Wall Section	1mm	None

Note 1: Minimum of two (2) implants allowed in mandible without distal extensions and having soft tissue support.
Note 2: No distal cantilevers allowed for bars with 2 or 3 implants. When using an attachment on the extension, a 2mm radius is required under the bar.

5. INDICATIONS FOR USE

Implant Direct Custom Bars are patient specific devices indicated for attachment to dental implants in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function.

Custom bars are compatible at the implant level with InterActive (3.4mm Platform) & SwishActive (3.4mm Platform) System implants.

Manufacturer	Implant Line	Body Diameter	Implant Platform
Implant Direct	InterActive	4.3mm, 5.0mm	3.4mm
Implant Direct	SwishActive	4.8mm	3.4mm

Custom bars are compatible at the abutment level with InterActive (3.4mm Platform) & SwishActive (3.4mm Platform) system straight multi-unit abutments.

Manufacturer	Implant Line	Implant Platform
Implant Direct	InterActive	3.4mm
Implant Direct	SwishActive	3.4mm

6. COMPARISON OF INDICATIONS FOR USE BETWEEN PROPOSED DEVICE AND PRIMARY PREDICATE

Characteristics	**Proposed Device** Custom Bars (K162633)	**Primary Predicate** ISUS Implant Suprastructure – Bars and Hybrids (K122424)
Indications for Use	Implant Direct Custom Bars are patient specific devices indicated for attachment to dental implants in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. Custom bars are compatible at implant level with InterActive (3.4mm Platform) (D4.3, D5.0) & Swish Active (3.4mm Platform) (D4.8) system implants.	The ISUS Implant Suprastructure are indicated for attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. The ISUS Implant Suprastructures are intended for attachment to a minimum of two(2) implants. ISUS Implant Suprastructures are indicated for compatibility with the following implant and abutment systems: Implants:

	Custom bars are compatible at abutment level with InterActive (3.4mm Platform) & Swish Active (3.4mm Platform) system .	* Nobel Biocare Replace Select: NP (3.5mm), RP (4.3mm), WP (5.0mm), and Replace Select 6.0mm * Nobel Biocare Active Internal: NP (3.5mm), RP (4.3mm, 5.0mm) *Zimmer Screw Vent: D3.5, D4.5, D5.7 *Straumann: NN (3.5mm), RN (4.8mm), WN (6.0mm) *Straumann Bone Level: NC (3.3mm), RC (4.1 mm, 4.8mm) *31 Internal Connection: D3.4, D4.1, D5, D6 *Friadent XiVE S: D3, D3.4, D3.8, D4.5, D5.5 Abutments: *ASTRA TECH- 20° and 45° UniAbutment *ASTRA TECH UniAbutmnent EV: 3.6 *ANKYLOS Balance Base Abutment D5.5 and Narrow Abutment D4.2 *Nobel Biocare Multi -Unit Abutment RP: 4.0 mm *Zimmer Tapered Abutment: 4.5mm *Straumann RN(4.Smm), WN (6.5 mm) *Straumann Bone Level: Multi-Base Abutment D3.5, D4.5 *Straumann Bone Level Angled Abutment:4.0 mm *31 Low Profile Abutment *Friadent XiVE MP D3.8, D4.5, D5.5 *Friadent XiVE TG D3.8, D4.5, D5.5

The intended use of the proposed Custom Bar is same as the primary predicate except for the interface compatibilities and customization parameters. The devices have differences in compatibility information and are specified within the Indications for Use. The proposed and predicate devices have differences in the customization parameters and are specified in the Instructions for Use. The device compatibility and customization parameters are supported by performance testing and do not affect substantial equivalence to the predicate.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Characteristics	**Proposed Device** Custom Bars	**Primary Predicate**	**Reference Device**	**Reference Device**

	(K162633)	ISUS Implant Suprastructure – Bars and Hybrids (K122424)	NobelProcera Overdenture Bar (K132749)	Biomet 3i CAM Structure Overdenture Bars (K101582)
Intended Use	Attachment to dental implants in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function.	Attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	Attachment to implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function.	Accessory to endosseous dental implants to support a prosthetic device in a partially or edentulous patient.
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity	Oral Cavity
General Design	One piece milled bar with fixation screws designed to interface with multi-unit abutments or implants.	One piece milled bar with fixation screws designed to interface with multi-unit abutments or implants	One piece milled bar with fixation screws designed to interface with multi-unit abutments or implants.	One piece milled bar with fixation screws designed to interface with multi-unit abutments or implants.
Bar Material	Titanium alloy	Titanium, Cobalt-Chromium Alloy	Titanium alloy	Titanium alloy
Design Method Bar Order	Individually designed for each patient by order of prescription	Individually designed for each patient by order of prescription	Individually designed for each patient by order of prescription	Individually designed for each patient by order of prescription
Restoration Type	Screw Retained Bar with Patient	Screw Retained Bar with Patient	Screw Retained Bar with Patient	Screw Retained Bar

	Removable Overdenture or Fixed Detachable Framework	Removable Overdenture or Fixed Detachable Framework	Removable Overdenture or Fixed Detachable Framework	with Patient Removable Overdenture or Fixed Detachable Framework
Bar Element Profiles	Metal Lingual, Traditional Hybrid, Y Bar, I Bar, Pawn Bar, Hader, Locator/GPS/Ball Bar	Round, Hader, Dolder (U) "non resilient", Dolder (Y) "resilient", Bredent, Bredent VSP f Bredent VSP fs, ISUS Custom	Dolder (Micro, Macro, Micro - Resilient, Macro - Resilient), Hader, Round, Free Form Milled, Paris Bar, Wrap-around Bar, Montreal Bar, Montreal with Metalic Lingual, Hybrid, Implant Bridge titanium, Implant Bridge Zirconia	Hybrid Bar, Wraparound Bar, Freeform Bar, Canada Bar, Dolder Egg Shape Bar, Dolder Ushape Bar, Hader, Primary Bar, Combination Primary/Hader /Dolder, Copymilled Bar/Framework
Screw Material	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile

The proposed device and predicates have the same general design, similar production methods, same size cylinder wall, allow for the same final restoration types, and have the same sterilization methods.

The differences between the proposed devices and the predicate devices have also been evaluated. The proposed bars have smaller allowable span, equivalent or smaller distal extension, smaller cylinder height, different bar profiles, and larger fixation screws. Performance testing has shown to support substantial equivalence to the reference predicate. Though the material used in subject device is different from the primary predicate, it is equivalent to that of the reference predicate. The differences in Custom Bar parameters and materials, used to construct the proposed device, do not affect substantial equivalence.

8. PERFORMANCE DATA

Non-clinical testing was performed on the proposed device. Testing include mechanical strength, biocompatibility, and cleaning and steam sterilization validation. Results indicated that the subject device is equivalent to the predicate device.

- Mechanical testing
  - Fatigue testing was performed on worst-case configuration per ISO 14801. Results indicated that the bar interface successfully completed endurance testing and was equivalent to the predicate device.
  - Bending strength testing was performed on worst-case bar according to a modified version of ASTM F382. Results indicated that the subject device is equivalent to the predicate device.

- Biocompatibility testing was performed per ISO 10993-1 and ISO 10993-5. Cytotoxicity testing and comprehensive biocompatibility evaluation was conducted. Results indicate that the device met all biocompatibility requirements for its intended use. The material of subject device conforms to FDA recognized consensus standard ASTM F136 and is equivalent to the reference predicate.

- The subject devices are provided non-sterile and to be end user sterilized. Steam sterilization validation was performed on the worst case sample per ISO 17665-1 and ISO 17665-2. Results indicated the acceptance criteria was met and the devices can be sterilized per Gravity Displacement and Pre-vacuum cycle parameters.

9. CLINICAL PERFORMANCE DATA

   Clinical Performance testing was not performed. Clinical data is not required to support substantial equivalence.

10. CONCLUSION

    Implant Direct Custom Bars are substantially equivalent to the legally marketed device(s) from Dentsply International ISUS Implant Suprastructures (K122424). The intended use, design features, and materials of the subject devices are equivalent to those of the predicate devices. The fundamental scientific technology of the modified devices has not changed relative to the predicates devices. The application is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this premarket notification. The subject device is substantially equivalent to the declared predicates.