June 30, 2020

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

Re: K200265
Trade/Device Name: Surgical Drills
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: DZI
Dated: March 31, 2020
Received: April 1, 2020

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,

for Srinivas “Nandu” 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K200265

Device Name
Surgical Drills

Indications for Use *(Describe)*

The Surgical Drills are intended to cut into maxilla or mandible to create an osteotomy for endosseous dental implant placement.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

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

Contact Person: Reina Choi, Regulatory Affairs Manager
E-mail: reina.choi@implantdirect.com
Phone: (818) 444-3306

Date Prepared: March 31, 2020

II. DEVICE

Name of Device: Surgical Drills
Common or Usual Name: Endosseous Dental Implant Drills
Classification Name: Bone cutting instrument and accessories (21 CFR 872.4120)
Regulatory Class: II
Product Code: DZI

III.PREDICATE DEVICE

Predicate (primary)
Straumann Guided Instruments (K082532)

Predicate (reference)
Swiss Plant Dental System (Surgical Drills) (K081396)

IV. DEVICE DESCRIPTION

The proposed Surgical Drills are reusable invasive surgical instruments designed to prepare an osteotomy for a dental implant procedure. The base material of the drill is made of surgical grade stainless steel. The bone cutting portion of the drill may be coated with diamond like coating (DLC) or laser marked to indicate the depth marks.

The Surgical Drills consist of straight drills, step drills, and cortical drills. Straight drills are available in diameters 3.2 to 5.1 mm. Step drills are available in diameters 2.3/2.0 to 5.4/4.8 mm. Cortical drills are available in diameters 3.2 to 7.0 mm. The straight and step drills have osteotomy depth indicators and are intended to make osteotomies for Implant Direct endosseous dental implants.

V. INDICATIONS FOR USE

The Surgical Drills are intended to cut into maxilla or mandible to create an osteotomy for endosseous dental implant placement.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Technological characteristics		Subject Device	Predicate (primary)	Predicate (reference)	Comparison
		Surgical Drills	Straumann Guided Instruments (K082532)	Swiss Plan Dental Implant System Surgical Drills (K081396)	
Manufacturer		Implant Direct Sybron Manufacturing, LLC	Institute Straumann AG	Implant Direct Sybron Manufacturing, LLC	Same as reference predicate
Design Characteristic	General design	Multiple cutting edges and flutes to create an osteotomy. Shank to fit with hand piece	Multiple cutting edges and flutes to create an osteotomy. Shank to fit with hand piece	Multiple cutting edges and flutes to create an osteotomy. Shank to fit with hand piece	Same
	Base material	Stainless steel	Stainless steel	Stainless steel	Same
	Coating	- No coating - DLC (diamond like coating)	No coating	No coating	Addition of DLC
	Cutting flutes	2 and 4 flutes	2 flutes	2 and 4 flutes	Same as reference predicate
	Handpiece connection shank type	ISO-1797-1	ISO-1797-1	ISO-1797-1	Same
	Irrigation	External only	External only	External only	Same
	Packaging	Plastic vial, supported by a plastic retainer	Loose inside a blister pack	Plastic vial, supported by a plastic retainer	Same as reference predicate
	Sterility	Non-sterile	Non-sterile	Non-sterile	Same
	Reusable or single use	Reusable	Reusable	Reusable	Same
Intended use		Bone cutting instruments are intended for use during oral surgery to drill or cut into the upper or lower jaw and may be used to prepare bone to insert	Bone cutting instruments are intended for use during oral surgery to drill or cut into the upper or lower jaw and may be used to prepare bone to insert	surgical drills used for the preparation of the surgical site prior to implantation	Same as primary predicate

Technological characteristics	Subject Device	Predicate (primary)	Predicate (reference)	Comparison
	Surgical Drills	Straumann Guided Instruments (K082532)	Swiss Plan Dental Implant System Surgical Drills (K081396)	
	a wire, pin or screw.	a wire, pin or screw.		
Indication for Use	The Surgical Drills are intended to cut into maxilla or mandible to create an osteotomy for endosseous dental implant placement.	Bone cutting instruments are intended for use during oral surgery to drill or cut into the upper or lower jaw and may be used to prepare bone to insert a wire, pin or screw.	The SwissPlant Dental Implant system consists of two-piece implants for one or two-stage surgical procedures that are intended for use in partially or fully edentulous mandibles and maxillae, in support of single - or multiple-unit restorations including: cement retained, screw retained or overdenture restorations and in terminal or immediate abutment support for fixed bridgework. The SwissPlant dental implants are intended for immediate placement and function on single tooth and/or multiple tooth applications recognizing initial implant stability and appropriate occlusal loading, to restore normal masticatory function.	Differences do not affect substantial equivalence. Refer to change analysis following this table.

Analysis of Differences Between Subject Device and Predicate

The Surgical Drills are made from the same materials and have the same general design and handpiece connection as both the primary and reference predicates. The Surgical Drills are delivered non-sterile and are intended for multiple use the same as the primary and reference predicates. The Surgical Drills differ from the predicates in the use of a DLC coating. The addition of the DLC coating was validated through the use of biocompatibility, corrosion, and functional wear testing.

The Surgical Drills and primary predicate have the same intended use.
Comparison of subject device and predicate device indications for use:

- The name of the device is changed from bone cutting instruments to Surgical Drills.
- Creating an osteotomy for the purpose of dental implant placement is a type of oral surgery.
- The subject Surgical Drills are used in the maxilla or mandible which is the same as the upper or lower jaw.
- The subject Surgical Drills are used to create osteotomy which is a preparation of the bone.
- The subject Surgical Drills are used to create an osteotomy for the purpose of placing a dental implant. A dental implant is a type of screw.

The above comparison details how the differences between the subject device indications for use and the predicate (K082532) device indications for use do not affect substantial equivalence.

Summary:
The design differences between the subject and predicate device was evaluated through biocompatibility, corrosion, and comparative wear testing. The documentation submitted in the premarket notification demonstrates that the Surgical Drills are substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

Summary of Non-Clinical Testing:

<u>Biocompatibility</u>
The Surgical Drills were successfully tested for biocompatibility testing in accordance with ISO 10993-1, ISO 10993-5, ISO 10993-10, and ISO 10993-11. The results of the testing were used to address questions related to substantial equivalence based on differences in manufacturing processes (addition of DLC coating) between the subject and predicate device (K082532).

<u>Performance testing</u>

Simulated osteotomies were created in simulated bone using the subject device and predicate device (K082532). Drilling axial force was recorded and cutting surfaces were assessed visually using SEM images. Results indicate no significant changes in axial drilling thrust forces in all three groups after repeated use and processing. The results of the testing were used to address questions related to substantial equivalence based on differences in device design between the subject and predicate device (K082532).

Corrosion testing

Corrosion testing (ASTM F1089) was successfully undertaken to ensure that Surgical Drills when processed in accordance with the Instructions for Use will not corrode. Worst-case drills were boiled for 30 minutes and allowed to cool and air dry. All tested Surgical Drills showed no sign of corrosion without magnification. The results of the testing were used to address questions related to substantial equivalence based on differences in manufacturing processes between the subject and predicate device (K082532).

Cleaning Validation

Cleaning efficiency was successfully conducted in accordance with AAMI TIR30 and AAMI TIR12. The study used a clinically-relevant, simulated soil, extended drying time between soiling and processing, and minimal processing parameters for the cleaning process. Extracts of proposed devices were analyzed for total organic carbon (TOC) and protein as residual soil markers. The results of the testing were used to address questions related to substantial equivalence based on differences in product use between the subject and predicate device (K082532).

Sterilization

Sterilization validation was successfully conducted in accordance with ISO 17665-1. The overkill approach as per ISO 17665-1 was used to demonstrate an SAL of 10^{-6}. The results of the testing were used to address questions related to substantial equivalence based on differences in product design between the subject and predicate device (K082532).

Distribution

The Surgical Drills were subjected to distribution testing to determine any impact distribution would have on the subject device. Worst-case drills were subjected to simulated shipping following ASTM D4169-16. Tests included handling, stacking, loose load vibration, vehicle vibration, concentrated impact, and an additional handling test. All drills subjected to the distribution testing passed the QA inspection prior to and after the distribution simulation. The results of the testing were used to address questions related to substantial equivalence based on differences in product packaging between the subject and predicate device (K082532)

VIII. CONCLUSIONS

The Surgical Drills were evaluated for substantial equivalence using standard and/or comparative testing. Based on technological characteristics and non-clinical test data included in this submission, the Surgical Drills have been shown to be substantially equivalent to the Straumann Guided Instruments (K082532).