January 22, 2021

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

Re: K201553
Trade/Device Name: Simply Iconic™ Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: December 22, 2020
Received: December 22, 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,

Andrew Steen
Assistant 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)*
K201553

Device Name
Simply Iconic™ Implants

Indications for Use *(Describe)*

Simply Iconic™ dental implants are 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 (3.2mmD) implants: Indicated for single-tooth replacement (mandibular central and lateral incisors; maxillary lateral incisors), multiple-tooth replacements or denture stabilization.
• Short (6mm) 3.7mmD implants: Indicated for single-tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.

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.

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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) 307-3132

Date Prepared: January 22, 2021

II. DEVICE

Name of Device: Simply Iconic™ Implants
Common or Usual Name: Endosseous Dental Implant
Classification Name: Implant, Endosseous, Root-Form (21 CFR 872.3640)
Regulatory Class: II
Product Code: DZE

III.PREDICATE DEVICE

Predicate (primary)
InterActive/SwishPlus2 Implant System (K130572)

Predicate (reference)
Spectra-System Dental Implants 2008 (K090234)
Legacy3 6mm Length Implants (K131097)

IV. DEVICE DESCRIPTION

The Simply Iconic™ implants are two-piece dental 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.

The top one-third (coronal part) of the Simply Iconic™ implant body is straight, with quadruple-lead micro-threads on the coronal aspect, and the lower two-thirds is tapered with dual-lead progressively deeper buttress threads. This design is intended for increased bone-to-implant contact (BIC). Three cutting flutes extend over the tapered portion of the implant body to make bone tapping unnecessary for implant insertion.

The dental implant body are available in several diameter sizes (ranging from 3.2mmD

– 7.0mmD), platform diameters (3.0, 3.4mmD) and lengths (ranging from 6 – 16 mm). These options are listed in **Table 1** below. These variations provide flexibility for clinicians to address patients' various bone structures/mouth anatomies.

Table 1: Dimensions for Simply Iconic™ Implants

Body Diameter	Platform Diameter	Length
3.2mmD	3.0mmD	8, 10, 11.5, 13, and 16 mm
3.7mmD	3.0mmD	6, 8, 10, 11.5, 13, and 16 mm
4.2mmD	3.0mmD	6, 8, 10, 11.5, 13, and 16 mm
4.7mmD	3.0mmD	6, 8, 10, 11.5, 13, and 16 mm
4.7mmD	3.4mmD	6, 8, 10, 11.5, 13, and 16 mm
5.2mmD	3.4mmD	6, 8, 10, 11.5, and 13 mm
5.7mmD	3.4mmD	6, 8, 10, 11.5, and 13 mm

The Simply Iconic™ dental implants utilize the same implant abutment interface as the Implant Direct InterActive implants and are compatible with corresponding 3.0 and 3.4 mm platform InterActive abutments.

The Simply Iconic™ dental implants are composed of titanium 6Al4V ELI metal, anodized titanium 6Al4V ELI colors (magenta or gold), Soluble Blast Media (SBM) surface treatments with Hydroxyapatite (HA) blast media. SBM implant surfaces have a micro texture created on defined areas of the implant. The Simply Iconic™ dental implants are packaged sterile supplied with a cover screw and a 5mm healing collar.

V. INDICATIONS FOR USE

Simply Iconic™ dental implants are 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 (3.2mmD) implants: Indicated for single-tooth replacement (mandibular central and lateral incisors; maxillary lateral incisors), multiple-tooth replacements or denture stabilization.
- Short (6mm) 3.7mmD implants: Indicated for single-tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS (SUBJECT DEVICE AND PRIMARY PREDICATE)

Technological characteristics		Subject Device Simply Iconic™ Implants (K201553)	Predicate (primary) InterActive/SwishPlus2 Implant System (K130572)	Comparison
Manufacturer		Implant Direct Sybron Manufacturing, LLC	Implant Direct Sybron Manufacturing, LLC	Same
Design Characteristic	General design	Threaded root form implant	Threaded root form implant	Same
	Material	Titanium 6AL4V ELI	Titanium 6AL4V ELI	Same
	Coating/Surface Treatment	HA blasted SBM implants	- HA blasted SBM implants - HA blasted HA coated implants	The predicate includes SBM implants
	Body diameters	3.2, 3.7, 4.2, 4.7, 5.2, 5.7mm	3.2, 3.7, 4.3, 5.0mm	The subject device has 5.2 and 5.7mm diameter implants outside the scope of the predicate
	Body Lengths	6, 8, 10, 11.5, 13, 16mm	6, 8, 10, 11.5, 13, 16mm	Same
	Implant Platform and connection type	3.0 and 3.4mm platform with internal hex and conical connection	3.0 and 3.4mm platform with internal hex and conical connection	Same connector design and size
	Screw size	M1.6 and M2	M1.6 and M2	Same screw designs
Intended use		Simply Iconic™ Implant 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 of multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework.	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 of multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework.	Same intended use except for device name

Technological characteristics	Subject Device	Predicate (primary)	Comparison
	Simply Iconic™ Implants (K201553)	InterActive/SwishPlus2 Implant System (K130572)	
Indication for Use	Simply Iconic™ dental implants are 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 (3.2mmD) implants: Indicated for single-tooth replacement (mandibular central and lateral incisors; maxillary lateral incisors), multiple-tooth replacements or denture stabilization. • Short (6mm) 3.7mmD implants: Indicated for single-tooth (mandibular and maxillary central and lateral incisors), 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. Compatibility: 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	Both implants are two-piece for one stage or two stage procedures. Both implants are intended for 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 Both implants are indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading Both implants limit narrow diameter implants to single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors and for multiple tooth replacement and denture stabilization The subject device limits 6mm 3.7D implants to single-tooth mandibular and maxillary central and lateral incisors, multiple tooth replacements or denture stabilization. The subject device excludes 6mm implants for use with titanium custom abutments.

Technological characteristics	Subject Device	Predicate (primary)	Comparison
	Simply Iconic™ Implants (K201553)	InterActive/SwishPlus2 Implant System (K130572)	
		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 predicate specifies compatibility devices not placed on the market by Implant Direct. The subject device does not make such compatibility claims.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS (SUBJECT DEVICE AND REFERENCE PREDICATES)

Technological characteristics		Subject Device	Predicate (reference)	Predicate (reference)	Comparison
		Simply Iconic™ Implants (K201553)	Spectra-System Dental Implants 2008 (K090234)	Legacy3 6mm Length Implants (K131097)	
Manufacturer		Implant Direct Sybron Manufacturing, LLC	Implant Direct Sybron Manufacturing, LLC	Implant Direct Sybron Manufacturing, LLC	Same
Design Characteristic	General design	Threaded root form implant	Threaded root form implant	Threaded root form implant	Same
	Material	Titanium 6AL4V ELI	Titanium 6AL4V ELI	Titaniuu 6AL4V ELI	Same
	Coating/Surface Treatment	HA blasted SBM implants	HA blasted SBM Implants	HA blasted SBM implant	Same
	Body diameters	3.2, 3.7, 4.2, 4.7, 5.2, 5.7mm	3.2, 3.7, 4.2, 4.7, 5.2, 5.7mm	3.7, 4.2, 4.7, 5.2, 5.7, 7.0mm	Body diameter of subject device is the same as K090234
	Body Lengths	6, 8, 10, 11.5, 13, 16mm	8, 10, 11.5, 13, 16mm	6mm	Body length of subject device is within the range of the reference devices.
	Implant Platform and connection type	3.0 and 3.4mm platform with internal hex and conical connection	3.0, 3.5, 4.5, 5.7mm with internal hex and bevel connection	3.5, 4.5, 5.7mm with internal hex and bevel connection	Subject device uses internal hex like both reference devices. Subject device

Technological characteristics	Subject Device	Predicate (reference)	Predicate (reference)	Comparison
	Simply Iconic™ Implants (K201553)	Spectra-System Dental Implants 2008 (K090234)	Legacy3 6mm Length Implants (K131097)	
				platform size is within range of the reference devices
Screw size	M1.6 and M2	M1.6 and 1-72 UNF	1-72 UNF	Screw sizes of subject and reference predicates are comparable.

Analysis of Differences Between Subject Device and Predicates

The Simply Iconic™ dental implants are made from the same materials having same surface treatment with identical prosthetic interfaces and general design features as the primary and reference predicates.

The Simply Iconic™ dental implants differ from primary predicate (K130572) by offering additional body diameters to provide end users with a wider range of options. The Simply Iconic™ implants also offer a longer quadruple lead threads in the coronal region, similarly to the reference predicates, instead of offering micro grooves as in the primary predicate device, which allows for slightly higher insertion torque in soft-bone protocols and a higher pullout retention force for better initial worst-case engagement with bone.

Except for the device name the intended use of the primary predicate (K130572) and subject device Simply Iconic™ are the same. The subject device indications for use differs from the primary predicate (K130572) in two ways. First, the subject device limits narrow 3.2D implants and 6mm 3.7D implants to single-tooth mandibular and maxillary central and lateral incisors, multiple tooth replacements or denture stabilization. Second, the primary predicate specifies compatibility devices not placed on the market by Implant Direct. The subject device does not make such compatibility claims. Refer to the comparison table for a detailed comparison of the primary predicate (K130572) and subject device indications for use.

Summary:
The design differences between the subject and predicate device was evaluated through biocompatibility, sterilization, shelf life, simulated distribution, fatigue, surface area and bone-to-implant analysis, simulated pull out testing, and insertion torque testing. The documentation submitted in the premarket notification demonstrates that the Simply Iconic™ Implants are substantially equivalent to the predicate device.

VII. PERFORMANCE DATA

Summary of Non-Clinical Testing:

Biocompatibility
The Simply Iconic™ Implants were evaluated for biocompatibility in accordance with ISO 10993-1 and the subject devices were successfully tested for Cytotoxicity per ISO 10993-5, Irritation and Sensitization per ISO 10993-10, Systemic Toxicity and Chronic Toxicity per ISO 10993-11 (with the exception of material-mediated pyrogen testing as the subject devices not being represented to be non-pyrogenic devices), Implantation per ISO 10993-6, as well as Genotoxicity and Carcinogenicity per ISO 10993-3. The results demonstrated that the subject devices are considered biocompatible and pose no anticipated risk to the patient for

the intended clinical application. The endotoxins level is determined based on LAL test in accordance with ANSI/AAMI ST72 and is performed twice a year for final products and with every new product manufactured on site per United States Pharmacopeia Convention, Inc. USP <85> and <161>. The testing limit is 20 EU per device or 0.5 EU per ml respectively in accordance with the requirements set out in FDA Guidance *"Pyrogen and Endotoxins Testing: Questions and Answers."* 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 (K130572).

Distribution

The Simply Iconic™ Implants were subjected to distribution testing to determine any impact distribution would have on the subject device. Worst-case implants were subjected to simulated shipping following ASTM D4169, DC 13, Assurance Level II. Tests included handling, stacking, loose load vibration, vehicle vibration, concentrated impact. All implant 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 (K130572)

Fatigue testing

The Simply Iconic™ Implants were subjected to fatigue performance testing according to *ISO 14801 Dynamic Loading Test for Endosseous Dental Implants,* and Section 8 of *"Guidance for Industry and FDA Staff" - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*. Results were favorably compared to both primary and reference predicates. 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 (K130572) as well as the reference predicate device (K090234).

Surface area and bone-to-implant contact analysis

The Simply Iconic™ Implants were subjected to surface area and bone-to-implant contact analysis. Both surface area and bone-to-impact comparisons were made to the primary predicate (K130572) and reference predicate (K131097) 6mm length implant designs. Results of the analysis showed that the subject device has greater surface area and bone-to-implant contact than the predicate. The results of the testing were used to address questions related to substantial equivalence based on differences in product design between the subject and primary predicate device (K130572) as well as the reference predicate device (K131097).

Simulated pullout testing

The Simply Iconic™ Implants were subjected to simulated pullout testing. Osteotomies were made in simulated bone and subject device, primary predicate (K130572) 6mm length implants, and reference predicate (K131097) 6mm length

implants were inserted to a depth of 3mm below the implant bone level. The force required to remove the implants was recorded. Results of the testing showed that the subject device has greater pullout force than the predicates. The results of the testing were used to address questions related to substantial equivalence based on differences in product design between the subject and primary predicate device (K130572) as well as the reference predicate device (K131097).

Insertion torque testing

The Simply Iconic™ Implants were subjected to insertion torque testing. Osteotomies were made in simulated bone and subject device, primary predicate (K130572) 6mm length implants, and reference predicate (K131097) 6mm length implants were inserted. The torque required to place the implants was recorded. Results of the testing showed that the subject device has comparable insertion torque as the predicates. The results of the testing were used to address questions related to substantial equivalence based on differences in product design between the subject and primary predicate device (K130572) as well as the reference predicate device (K131097).

Sterilization testing

The Simply Iconic™ Implants were subjected to sterilization testing. Sterilization validation testing was performed per ISO 11137-2 to verify the ability of Implant Direct's established VDmax radiation sterilization process. The validation successfully demonstrated a sterility assurance level (SAL) of 10^{-6} for the subject devices. The results of the testing were used to address questions related to substantial equivalence based on differences in product design between the subject and primary predicate device (K130572).

Shelf life Validation

The real-time shelf life validation was conducted on the equivalent devices with same sterile barrier packaging system per ISO 11607-1 and the results verified that the Simply Iconic™ Implants can maintain sterility for 5 years per ISO 11737-1 and ISO 11737-2. The results of the testing were used to address questions related to substantial equivalence based on differences in product design between the subject and primary predicate device (K130572) as well as the reference predicate device (K090234).

VIII. CONCLUSIONS

The Simply Iconic™ Implants 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 Simply Iconic™ Implants have been shown to be substantially equivalent to the InterActive/SwishPlus2 Implant System (K130572).