June 25, 2020

Implant Direct Sybron Manufacturing, LLC
% Kelliann Payne
Partner
Hogan & Lovells US LPP
1735 Market Street
Floor 23
Philadelphia, Pennsylvania 19103

Re: K192221
Trade/Device Name: Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 27, 2020
Received: May 27, 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)*

K192221

Device Name

Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts

Indications for Use *(Describe)*

Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 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 (<10mm) 3.7mm implants: Indicated for single-tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.

The Legacy 2, Legacy3, and Legacy4 fixture-mounts are intended for use with the corresponding dental implants (Legacy2, Legacy3, and Legacy4, respectively). The fixture-mounts can function as an abutment. As an abutment, fixture-mounts are 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.

- Fixture-mounts as an abutment for narrow (3.2mmD) implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
- Fixture-mounts as an abutment for short (8mm) 3.7mmD implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.

Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 implants are compatible with the following abutments.

Manufacturer	Abutment Line	Platform Diameter
Implant Direct	Legacy	3.0mm, 3.5mm, 4.5mm, 5.7mm

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 LLC's

Legacy2, Legacy3, Legacy4, simplyLegacy2, and simplyLegacy3 Dental Implants; Legacy2, Legacy3, and Legacy4 Fixture-mounts

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:	June 25, 2020
Name of Device:	Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture-mounts
Common or Usual Name:	Endosseous dental implants
Classification Name:	21 C.F.R. § 872.3640 (*Endosseous dental implants*);
Regulatory Class:	Class II
Primary Product Code:	DZE
Secondary Product Code:	NHA
Predicate Device:	Implant Direct LLC's Spectra-System Dental Implants 2008 (now Legacy3 Dental Implant) (K090234)
Reference Devices:	Implant Direct LLC's Legacy3 Implants (6mm Length) (K131097); Implant Direct LLC's Legacy Abutment System (K060063); Implant Direct LLC's Custom Legacy and Custom InterActive Titanium Abutments (K192218)

Device Description

The Legacy2, Legacy4, and simplyLegacy2 implants have the same implant body and are supplied in similar dimensions. This 510(k) notice includes the Legacy3 dimensions previously cleared in K090234 and K131097; the Legacy3 (7.0mmD) is the same as the previously cleared Legacy3, but in a wider diameter.

The top approximate one-third of the implant body is straight, and the lower approximate two-thirds is tapered with progressively deeper buttress-threads. The Legacy3 implant body also features progressively deeper buttress threads, with quadruple-lead micro-threads at the coronal aspect; this implant body is evenly tapered. Each implant features a color-coded internal hex with a lead-in bevel. The simplyLegacy2 and simplyLegacy3 implants are identical to the Legacy2 and Legacy3 implants, respectively, except that they are supplied without the corresponding fixture-mount/abutment.

The table below outlines the body diameters, platform diameters, and lengths in which each Legacy implant model is available.

Dimensions of Subject Implants

Subject Implants	Body Diameter	Platform Diameter	Implant Length
Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, Legacy4	3.2mmD	3.0mmD	8, 10, 11.5, 13, 16mm
	3.7mmD	3.5mmD	6 (only simplyLegacy), 8, 10, 11.5, 13, 16mm
	4.2mmD	3.5mmD	
	4.7mmD	4.5mmD	
	5.2mmD	4.5mmD	
	5.7mmD	5.7mmD	
	7.0mmD	5.7mmD	6 (only simplyLegacy), 8, 10, 11.5, 13mm

The Legacy2 and Legacy3 implants have a one-piece fixture-mount, and the Legacy4 implant has a two-piece fixture-mount. The Legacy fixture-mounts serve (1) as a transfer, to carry the implant to the osteotomy and help with placement if desired; (2) to take an impression after implant placement, to guide fabrication of the patient-specific dental restoration; and (3) as an abutment.

All of the subject devices are made of Titanium alloy, are single-use, and come into contact with patient tissue/bone for a long-term or permanent duration. The implants are supplied with one of two surface modifications/coatings:

- Soluble Blast Media (SBM);
- Hydroxyapatite (HA) per ASTM F1185.

Legacy2, Legacy3, and Legacy4 implants are available with either surface modification/coating; simplyLegacy2 and simplyLegacy3 are only available with SBM.

The devices are supplied sterile; the fixture-mounts, if modified for use as abutments, must also be sterilized by the end user prior to intra-oral use.

Intended Use / Indications for Use

Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 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 (<10mm) 3.7mm implants: Indicated for single-tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization.

The Legacy 2, Legacy3, and Legacy4 fixture-mounts are intended for use with the corresponding dental implants (Legacy2, Legacy3, and Legacy4, respectively). The fixture-mounts can function as an abutment. As an abutment, fixture-mounts are 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.

- Fixture-mounts as an abutment for narrow (3.2mmD) Implants: Indicated for single-tooth

replacement of mandibular central and lateral incisors and maxillary lateral incisors.

- Fixture-mounts as an abutment for short (8mm) 3.7mmD implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.

Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 implants are compatible with the following abutments.

Manufacturer	Abutment Line	Platform Diameter
Implant Direct	Legacy	3.0mm, 3.5mm, 4.5mm, 5.7mm

Summary of Comparison to Predicate Device

The minor differences in indications between the subject and predicate devices are not critical to the intended therapeutic use of the products and do not raise different questions of safety or effectiveness when the products are used as labeled, because they merely limit the scope of use and clarify the appropriate conditions of use. Relatedly, this submission updates the indications for use statement for the previously cleared Legacy3 implant models (K090234 and K131097) to align with the indications for the other subject Legacy models.

Both the subject and predicate implants function in support of single- and multi-unit restorations to help rehabilitate partially and fully edentulous patients' chewing function. Both implants are indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. The underlying technological principle is mechanical load-bearing of the forces imparted in the patient's mouth in order to provide stability. While the devices differ slightly in specific features of the implant body, the core design and how it functions are the same. Similarly, the subject fixture-mounts and the predicate Legacy3 straight abutment are made of the same materials and function in the same way to support dental restorations in conjunction with a corresponding implant. The minor differences in certain dimensions of the subject fixture-mounts and to incorporate the additional class I, exempt functionalities (implant carrier and transfer) do not alter the principles of operation of the system or the related safety and efficacy considerations.

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

Performance Data

The company performed the following bench testing in support of the subject devices' safety and effectiveness:

- Fatigue Testing

  The subject devices were subjected to cyclic fatigue testing in accordance with ISO 14801:2016 and FDA's *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*, and also leveraged fatigue testing conducted on representative devices (submitted in K192218). Results were favorable compared to the predicate and reference device and demonstrate that the subject devices can withstand foreseeable mastication forces in accordance with their specifications when used as intended.

- Biocompatibility Testing

  Representative, worst-case subject devices were successfully tested for biocompatibility in accordance with ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10, ISO 10993-11 and FDA's corresponding June 2016 guidance. The following endpoints were tested: cytotoxicity; sensitization; irritation; systemic toxicity; implantation (considered to also

cover sub-acute/sub-chronic and chronic toxicity); and genotoxicity/mutagenicity.

- Surface Area and Bone-to-Implant Contact Analysis

  Both surface area and bone-to-implant contact comparisons were made between the subject implants and reference device (K131097) 6mm length implants. Results show that the subject devices are substantially equivalent with respect to surface area and bone-to-implant contact.

- Pull-out Testing

  Osteotomies were made in simulated soft bone. The subject and reference device 6mmL implants were inserted to a depth of 3mm below the bone level. Results show that the force required to pull out the 6mmL subject implants was substantially equivalent to that for the reference device.

- Insertion Torque Testing

  Osteotomies were made in simulated soft and dense bone; subject and reference device 6mmL implants were inserted. Results show that the subject 6mmL devices have comparable insertion torque as the reference 6mmL device.

- Sterilization Validation Testing

  Sterilization validation testing was performed on worst-case representative subject devices in accordance with ISO 11137-2. The validation successfully demonstrated a sterility assurance level (SAL) of 10^{-6} for the subject devices.

- Endotoxin Testing

  Bacterial endotoxin (LAL) testing was performed per ANSI/AAMI ST72 on worst-case representative subject devices to verify that the subject implants, upon terminal sterilization, meet established endotoxin release limits. Results were well below the maximum thresholds set by FDA and USP, confirming that the devices are acceptably non-pyrogenic.

- Shelf Life Validation

  The subject devices after 5 years of real time aging were subjected to microbial aerosol challenge and sterility testing in accordance with ISO 11737-2. Results were passing in support of the labeled shelf life – the device label remained attached and legible, there was no damage to the device or packaging due to aging, and the sterile barrier remained intact.

- Distribution Validation

  To determine any impact distribution would have on the subject device, worst-case implants underwent simulated shipping following ASTM D4169, DC 13, Assurance Level II. Tests include handling, stacking, loose load vibration, vehicle vibration, and concentrated impact. All tested implants passed post-simulation quality and sterile barrier inspection.

- Sterilization Validation

  Sterilization validation performed for K192218 on devices representing worst-case compared to the subject fixture-mount/abutments in accordance with ANSI/AAMI/ISO 14937 and ISO 17665 was relied upon. This testing confirmed the adequacy of the steam sterilization process (performed by the end user on the fixture-mount/abutment per instructions/parameters provided in the device's labeling) to achieve a sterility assurance level (SAL) of 10^{-6} for the subject fixture-mount/abutments.

All results confirmed the devices' adequacy for their intended use and equivalent safety and effectiveness to the predicate device.

No animal or clinical studies were performed in support of this 510(k) notice.

Conclusions

The Legacy2, Legacy3, Legacy4, simplyLegacy2, and simplyLegacy3 dental implants and the Legacy2, Legacy3, and Legacy4 fixture-mounts are as safe and effective as the predicate Legacy3 implant system (K090234). The subject devices have the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate device. The minor differences in indications do not alter the intended therapeutic use of the devices and do not affect their safety and effectiveness when used as labeled. In addition, the minor technological differences between the subject devices and their predicate raise no new issues of safety or effectiveness. Performance data demonstrate that the subject devices are as safe and effective as the predicate. Thus, the subject Legacy dental implants and fixture-mount/abutments are substantially equivalent.

Substantial Equivalence Table

Characteristic	Legacy2, Legacy4, simplyLegacy2, Legacy3, and simplyLegacy3 Implants; Legacy2, Legacy3, Legacy4 Fixture-mounts	Predicate (K090234): Spectra-System Dental Implants 2008	Reference (K131097): Legacy3 Implants (6mmL)	Reference (K060063): Legacy Abutment System	Reference (K192218): Custom Legacy and Custom InterActive Titanium Abutments
Classification	21 C.F.R. § 872.3640; DZE 21 C.F.R. § 872.3630; NHA	21 C.F.R. § 872.3640; DZE		21 C.F.R. § 872.3630; NHA	21 C.F.R. § 872.3630; NHA
Intended Use / Indications for Use	Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 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 (<10mm) 3.7mm implants: Indicated for single-tooth (mandibular and maxillary central and lateral incisors), multiple tooth replacements or denture stabilization. The Legacy 2, Legacy3, and Legacy4 fixture-mounts are intended for use with the corresponding dental implants (Legacy2, Legacy3, and Legacy4, respectively). The fixture-mounts can function as an abutment. As an abutment, fixture-mounts are 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. • Fixture-mounts as an abutment for narrow (3.2mmD) implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. • Fixture-mounts as an abutment for short (8mm) 3.7mmD implants: Not intended for tooth replacement of canines, pre-	The Spectra-System Dental Implant 2008 system is comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The Dental Implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single-tooth or multiple-tooth restorations, recognizing bone stability and appropriate occlusal load requirements.	Legacy3 6mm Length implants consist 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.	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 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 claiming compatibility to the modified Zimmer Dental Screw-Vent implants.	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. Custom InterActive Titanium Abutments are compatible at the implant-level with InterActive, simplyInterActive and

Characteristic	Legacy2, Legacy4, simplyLegacy2, Legacy3, and simplyLegacy3 Implants; Legacy2, Legacy3, Legacy4 Fixture-mounts	Predicate (K090234): Spectra-System Dental Implants 2008	Reference (K131097): Legacy3 Implants (6mmL)	Reference (K060063): Legacy Abutment System	Reference (K192218): Custom Legacy and Custom InterActive Titanium Abutments
	molars or molars. Legacy2, simplyLegacy2, Legacy3, simplyLegacy3, and Legacy4 implants are compatible with Legacy abutments (3.0mm, 3.5mm, 4.5mm, 5.7mm platform).				SwishActive implants, excluding 6mm length implants.
General Design	Threaded Root form implant	Threaded Root form implant		Screw- or cement-retained root form abutment	Cement-retained root form abutment
Body Diameters	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm	3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	N/A	N/A
Implant Lengths	6mm (only simplyLegacy), 8mm, 10mm, 11.5mm, 13mm, 16mm	8mm, 10mm, 11.5mm, 13mm, 16mm	6mm	N/A	N/A
Cutting Flutes	3 (Legacy2/4); 2 (Legacy3)	2		N/A	N/A
Implant Platform	3.0mm, 3.5mm, 4.5mm, 5.7mm	3.0mm, 3.5mm, 4.5mm, 5.7mm	3.5mm, 4.5mm, 5.7mm	Mates with 3.5mm, 4.5mm, 5.7mm interface diameter	Mates with 3.0mm, 3.4mm, 3.5mm, 4.5mm, 5.7mm interface diameter
Connection Type	Internal hex	Internal hex	Internal hex	Internal hex	Internal hex
Screw Size	M1.6 and 1-72 UNF 2A	M1.6 and 1-72 UNF 2A	1-72 UNF 2A	M1.6, 1-72UNF	M1.6, M2, 1-72UNF
Implant Assembly	Implant is assembled with one-piece (Legacy2, 3) or two-piece (Legacy4) fixture-mount. simplyLegacy2, 3: No carrier or fixture-mount.	Implant is assembled with an abutment; carrier and transfer.		Abutment is assembled with compatible implant (corresponding size)	Abutment is assembled with compatible implant (corresponding size)
Sterilization	Supplied sterile; fixture-mounts sterilized by end user when used as abutments.	Supplied sterile; prosthetic components sold non-sterile and steam sterilized by end user prior to use.		Sterilized by end user	Sterilized by end user
Materials	Titanium 6AL4V ELI	Titanium 6AL4V ELI		Titanium 6AL4V ELI	Titanium 6AL4V ELI
Surface below bone level	SBM implant: HA blasted; HA implant: HA blasted/HA coated	SBM implant: HA blasted; HA implant: HA blasted/HA coated		N/A	N/A