February 2, 2023

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

Re: K222211
Trade/Device Name: Implant Direct Dental Implant Systems Portfolio - MR Conditional
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 5, 2023
Received: January 6, 2023

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 I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Simply Iconic™ Implants (previously cleared per K201553)

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)

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510(k) Number *(if known)*

Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3 dental implants; Legacy2, Legacy3, Legacy4 fixture- mounts (previously cleared per K192221)

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)

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Custom Legacy and Custom InterActive Titanium Abutments (previously cleared per K192218)

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.

Implant Line	Body Diameter	Platform Diameter	Implant Length
Legacy1	3.7mm, 4.2mm, 4.7mm, 5.7mm	3.5mm, 4.5mm, 5.7mm	8mm to 16mm
Legacy2, Legacy3, Legacy4, simplyLegacy2, simplyLegacy3	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	3.0mm, 3.5mm, 4.5mm, 5.7mm	

Custom InterActive Titanium Abutments are compatible at the implant-level with InterActive, SimplyInterActive and SwishActive implants, excluding 6mm length implants.

Implant Line	Body Diameter	Platform Diameter	Implant Length
InterActive, simplyInterActive	3.2mm, 3.7mm, 4.3mm, 5.0mm	3.0mm, 3.4mm	8mm to16mm
SwishActive	3.3mm, 4.1mm, 4.8mm	3.0mm, 3.4mm	8mm to16mm

Type of Use *(Select one or both, as applicable)*

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Legacy™ SMARTBase Abutments (previously cleared per K191458)

The Legacy™ SMARTBase Abutment system is designed to be used in support of a dental implant(s) to provide support for prosthetic restorations in a partially edentulous patient. Legacy SMARTBase engaging abutments are intended for use in the mandible or maxilla in support of single unit restorations.

The Legacy SMARTBase Abutment system integrates multiple components for use in both a traditional and digital dentistry workflow: scan files from Intra-oral Scanners and lab scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. The Legacy SMARTBase system consist of two major parts: the titanium base and zirconia top components make up a two-piece abutment.

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

Compatibility

Legacy SMARTBase engaging abutments are compatible at the implant level with Legacy (3.0mm, 3.5mm, 4.5mm and 5.7mm platform diameter) implants, excluding 6mm length implants.

Implant Line	Body Diameter	Platform Diameter	Implant Length
Legacy1	3.7mm, 4.2mm, 4.7mm, 5.7mm	3.5mm, 4.5mm, 5.7mm	8mm, 10mm, 11.5mm, 13mm, 16mm
Legacy2, 3, 4, simplyLegacy2, simplyLegacy3	3.2mm, 3.7mm, 4.2mm, 4.7mm, 5.2mm, 5.7mm, 7.0mm	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)

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510(k) Number *(if known)*

Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
InterActive SMARTBase Abutments (previously cleared per K181359)

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)*

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Custom Bars (previously cleared per K162633)

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)*

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
GPS® Angled Abutments (previously cleared per K153509)

GPS® Angled Abutments are designed to be used in support of a dental implant(s) to provide support for prosthetic restorations in a partially or completely edentulous patient. These abutments are designed to only receive a fabricated multi-unit bridge or overdenture. Abutments are intended for use in the mandible or maxilla. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

Compatibility:

- Legacy System: Prosthetically compatible with Zimmer Dental Tapered Screw-Vent system 3.5mm platform implants (3.7mmD, 4.1mmD, 8mm-16mm Length), 4.5mm platform implants (4.7mmD, 8mm-16mm Length), and 5.7mm platform implants (6.0mmD, 8mm-16mm Length).
- SwishTapered System: Prosthetically compatible with Straumann Standard and Standard Plus system RN platform implants (3.3mmD-4.8mmD, 6mm-16mm Length) and WN platform implants (4.8mmD, 6mm-12mm Length).
- SwishPlus System: Prosthetically compatible with Straumann Standard and Standard Plus system RN platform implants (3.3mmD-4.8mmD, 6mm-16mm Length) and WN platform implants (4.8mmD, 6mm-12mm Length).
- SwishActive Implants: 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) titanium 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) titanium 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 System: InterActive 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) titanium 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.

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)

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510(k) Number *(if known)*

Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
2014 InterActive/SwishActive System (previously cleared per K143011)

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.

Compatibility: 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) titanium 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.

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)

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Legacy3 6mm Length Implants (previously cleared per K131097)

Legacy3 6mm Length consists of two-piece implants for one-stage or two-stage surgical procedures. There 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.

Type of Use *(Select one or both, as applicable)*

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
InterActive/SwishPlus2 Implant System (previously cleared per K130572)

lnterActive/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: lnterActive and SwishPlus2 implants are prosthetically compatible with lnterActive 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. lnterActive 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.

Type of Use *(Select one or both, as applicable)*

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510(k) Number *(if known)*

Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Spectra-System Dental Implants 2008 (previously cleared per K090234)

Spectra-System Dental Implants 2008 are comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The 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.

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)

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510(k) Number *(if known)*

Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Swiss Dental Implant System (previously cleared per K081396)

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.

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)

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Indications for Use

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510(k) Number *(if known)*

Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Spectra-System Abutments 2008 (previously cleared per K081101)

Spectra-System Abutments are designed to be used in support of a dental implant(s) to provide support for prosthetic restorations such as crowns, bridges, overdentures or custom prosthetic fabrications in a partially or completely edentulous patient. Spectra-System Abutments are intended for use in the mandible or maxilla. Prostheses can be screw or cement retained to the abutment.

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)

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
ReActive Dental Implant System (previously cleared per K080713)

The ReActive Dental Implant System are dental implant fixtures that are a part of a two-piece implant system. The ReActive implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.

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)

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510(k) Number *(if known)*

Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
ScrewIndirect Narrow Dental Implants (previously cleared per K080633)

Screwlndirect Narrow Dental Implants are implants for single-stage surgical procedures intended for use in partially or fully edentulous mandibles and maxillae, in support of complete or partial denture prostheses or as a terminal or intermediary attachment for fixed or removable bridgework via interface with copings. These implants are intended for immediate loading for support of splinted multiple tooth restorations, provided initial implant stability and appropriate occlusal load requirements are met.

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)

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510(k) Number *(if known)*

Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
RePlus Dental Implants With HA Coating (previously cleared per K073161)

The RePlus Dental Implants with HA coating are dental implant fixtures that are a part of a two-piece implant system. The RePlus implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate loading for support of single tooth and/or multiple tooth restorations, provided initial implant stability and appropriate occlusal load requirements are met.

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)

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
ScrewPlus Dental Implants With HA Coating (previously cleared per K073049)

The ScrewPlus Dental Implant with HA coating is a dental implant fixture that is a part of a two-piece implant system that is to be used for single-stage or two-stage surgical procedures. The ScrewPlus implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.

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)

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Legacy Dental Implants With HA Coating (previously cleared per K073033)

The Legacy Dental Implant with HA coating is a dental implant fixture that is a part of a two-piece implant system. The Legacy implants are intended for use in the mandible and maxilla, in support of single or multiple-unit cement or screw receiving fixed restorations and for retention and support of overdentures. The implants are intended for immediate placement and function for support of single tooth and/or multiple tooth restorations, recognizing bone stability and appropriate occlusal load requirements.

Type of Use *(Select one or both, as applicable)*

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Spectra Dental Implant System (previously cleared per K061319)

The Spectra Dental Implant System consists of one-piece or two-piece implants for single-stage 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 and terminal or intermediate abutment support for fixed bridgework. They may be placed in immediate function if initial implant stability can be established.

The ScrewDirect 3.0mm implant is indicated for:

1. An artificial root structure for single tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors.
2. Multiple tooth replacements or denture stabilization.

The Screw Redirect implant is intended for support and retention of fixed single tooth and fixed partial denture restorations in the premolar, cuspid, and incisor regions of the partially edentulous maxillary jaw. It is indicated for immediate functional loading when four or more implants are splinted together in the endentulous upper or lower jaw.
The Screw Indirect implant is indicated for the support and retention of bar overdentures or as a terminal or intermediary attachment for screw-retained fixed bridgework. It is indicated for immediate functional loading when four or more implants are splinted together in the edentulous upper or lower jaw. This implant model is not indicated for use with abutments, only with a 2mm extender.

Type of Use *(Select one or both, as applicable)*

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Device Name
Implant Direct Dental Implant Systems Portfolio - MR Conditional

Indications for Use *(Describe)*
Legacy Abutment System (previously cleared per K060063)

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.

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)

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