



Food and Drug Administration
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Silver Spring, MD 20993-0002

August 26, 2016

Implant Direct Sybron Manufacturing, LLC
Ms. Renee Bennett
Regulatory Affairs Specialist
3050 East Hillcrest Drive
Thousand Oaks, California 91362

Re: K153509
Trade/Device Name: GPS[®] Angled Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: July 27, 2016
Received: July 28, 2016

Dear Ms. Bennett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the [Federal Register](#).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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

Sincerely yours,

 Tina Kiang
-S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K153509

Device Name
GPS® Angled Abutments

Indications for Use (Describe)

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) (3.5-5.0mmD, 8.5-18mmLength).
- 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
for
GPS® Angled Abutments

1. Submitter Information:

Company: Implant Direct Sybron Manufacturing LLC

Address: 3050 East Hillcrest Drive, Thousand Oaks,
CA 91362 USA

Contact Person: Renee Bennett
Telephone Number: 818-444-3348

Date Prepared: August 16, 2016

2. Device Name:

- Proprietary Name: GPS® Angled Abutments
- Classification Name: Endosseous Dental Implant Abutment
- CFR Number: 872.3630
- Device Class: II
- Product Code: NHA

3. Predicate Device:

Primary: GoDirect implants cleared under
K090234 - Spectra System Dental Implants
2008

Reference: Straight GPS abutments cleared
under *K130572 - InterActive/SwishPlus2*
Implant System

Reference: Screw Receiving abutment with
Ball top cleared under *K143011- 2014*
InterActive / SwishActive System

4. Description of Device:

GPS® Angled Abutments are designed to be used in conjunction with dental implant(s) to provide support for prosthetic restorations in a partially or completely edentulous patient. 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.

The proposed GPS® Angled Abutments are intended to provide extra prosthetic options currently unavailable to the clinician. The proposed abutments are intended to complement the cleared systems listed in **Table 2** below. The proposed abutments have the same compatible implant interface specific to each implant system and platform size.

TABLE 1: List of cleared Implant Direct systems and the proposed compatible GPS® angled abutments

#	System Name	510(k)	Proposed Compatible GPS® Abutments
1	InterActive SwishPlus2 Implant System	K130572	InterActive® SwishActive GPS Angled Abutments
2	Legacy Abutment System	K060063	Legacy GPS® Angled Abutments
3	Spectra System (RePlant)	K061319	Replant GPS® Angled Abutments
4	Swissplant Dental Implant System	K081396	Swish GPS® Angled Abutments

From **Table 1**, the worst case GPS® Angled abutment is the InterActive® /SwishActive GPS® Angled Abutment, 3.0 mm Platform. The 3.0 mm platform assembly represents the smallest size abutment from the InterActive system. Since the 3.4 mm implant and screw size is larger, the abutments are stronger than the 3.0 mm platform abutments. Hence, the 3.0 mm platform represents the worst case.

New fatigue testing has been completed on the worst case proposed GPS® Angled Abutment assembly..

The GPS® Angled abutments have the same coronal GPS Angled Top for all proposed GPS® Angled abutments. The GPS top has a superior outer radius at its coronal region that is identical to the primary predicate GoDirect implants (K090234 – Spectra System Dental Implants 2008). Since the proposed GPS® Angled abutments have the same coronal top design as the primary predicate GoDirect implants (K090234 – Spectra System Dental Implants 2008), the same compatibility will be achieved with the Zest

Locator® liner type attachments manufactured by Zest Anchor, Inc.

5. Indications for Use:

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) (3.5-5.0mmD, 8.5-18mmLength).
- 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.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics

The proposed Implant Direct Sybron Manufacturing LLC GPS® Angled abutments have the same intended use and technological characteristics and hence are shown to be substantially equivalent to the primary predicate device GoDirect implants (cleared under K090234 – Spectra System Dental Implants 2008). The proposed GPS Angled abutments and primary predicate GoDirect implants

(K090234) system contains both implants and abutments, and the intended use reflects this. The difference in the indications for use of the proposed devices and the primary predicate was due to the GoDirect implant being cleared with other Implant Direct implants (K090234), as part of the Spectra-System Dental Implants 2008. Also, the primary predicate was originally cleared with implants that are intended for both single unit and multi-unit restorations, while the proposed devices are only indicated for multi-unit bridge or overdentures and not for single unit restorations. Thus, the proposed devices have more limited indications for use than the primary predicate that does not alter the intended use for demonstration of substantial equivalence.

In addition, the reference predicate GPS Straight Abutments (cleared under K143011- 2014 InterActive / SwishActive System) and the reference predicate InterActive® Screw Receiving Overdenture abutment with a ball top (cleared under K130572 - InterActive/SwishPlus2 Implant System) are also considered substantially equivalent. The worst case proposed angled GPS abutment uses the same compatible implant interfaces, have the same thread size, same materials, same coatings, and same manufacturing processes as reference predicate abutments (K143011 - 2014 InterActive / SwishActive System).

The proposed GPS Angled abutments have the same coronal top features as the primary predicate GoDirect Implant (K090234 – Spectra System Dental Implants 2008) and reference predicate GPS Straight Abutments (cleared under K143011 - 2014 InterActive / SwishActive System). The proposed GPS® Angled abutments are a two-piece design having an identical lower piece with same interface features and angles as the reference predicate InterActive screw receiving angled abutments with a ball top (K130572 - InterActive/SwishPlus2 Implant System).

The proposed GPS® Angled Abutments differ from the primary predicate by having a two piece design with an angled body that utilizes a GPS top piece in order to have the same GPS compatibility with removable attachments.

These changes do not affect substantial equivalence of the proposed devices as demonstrated by internal performance and biocompatibility testing. GPS® Angled Abutment are substantially equivalent to the primary predicate GoDirect device cleared under (K090234 – Spectra System Dental Implants 2008) based on composition, performance and testing comparisons.

TABLE 2: Substantial Equivalence: Comparison of Proposed Device with Predicate on Technological Characteristics

Technological Characteristics	Proposed Device: GPS® Angled Abutment	Primary Predicate Device: GoDirect Implants (K090234 – Spectra System Dental Implants 2008)	Reference Predicate Device: Straight GPS Abutment (K143011 – 2014 InterActive/ SwishActive System)	Reference Predicate Device: InterActive® Swishplus2 Implant System (Abutment with Ball Top) (K130572 – InterActive/ SwishPlus2 Implant System)
Manufacturer	Implant Direct LLC	Implant Direct LLC	Implant Direct LLC	Implant Direct LLC
Regulation No.	21 CFR 872. 3630	21 CFR 872. 3640	21 CFR 872. 3640	21 CFR 872. 3640
Regulation Class	II	II	II	II
Product Code	NHA	DZE, NHA	DZE, NHA	DZE, NHA

<p>Technological Characteristics</p>	<p>Proposed Device: GPS® Angled Abutment</p>	<p>Primary Predicate Device: GoDirect Implants (K090234 – Spectra System Dental Implants 2008)</p>	<p>Reference Predicate Device: Straight GPS Abutment (K143011 – 2014 InterActive/SwishActive System)</p>	<p>Reference Predicate Device: InterActive® Swishplus2 Implant System (Abutment with Ball Top) (K130572 – InterActive/SwishPlus2 Implant System)</p>
<p>Indications for Use</p>	<p>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.</p>	<p>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 the use in the mandible and maxilla, in support of single unit or multiple unit cement or screw receiving restorations and for 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.</p>	<p>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.</p>	<p>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</p>

	<p>Compatibility:</p> <ul style="list-style-type: none"> •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). 			
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Technological Characteristics	Proposed Device: GPS® Angled Abutment	Primary Predicate Device: GoDirect Implants (K090234 – Spectra System Dental Implants 2008)	Reference Predicate Device: Straight GPS Abutment (K143011 – 2014 InterActive/ SwishActive System)	Reference Predicate Device: InterActive® Swishplus2 Implant System (Abutment with Ball Top) (K130572 – InterActive/ SwishPlus2 Implant System)
	<p>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) (3.5-5.0mmD, 8.5-18mmLength).</p>			

	<p>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.</p>			
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<p>General Design</p>	<p>2-piece abutment with a GPS top for compatibility with a snap-on cap attachment system and a implant engaging feature with 15 degree and 30 degree angled base.</p>	<p>GPS top integrated into coronal end of implant utilizing snap-on cap attachment systems.</p>	<p>1-piece abutment with a GPS top for compatibility with snap-on cap attachment system and with a threaded outer body to attach to implant.</p>	<p>2-piece abutment with a ball top for compatibility with a snap-on cap attachment system and a implant engaging feature with 15 degree and 30 degree angled base.</p>
<p>a) Fixation screw Design</p>	<p>Same</p>	<p>N/A</p>	<p>Different</p>	<p>Same</p>
<p>b) Lower piece design</p>	<p>Same</p>	<p>N/A</p>	<p>Different</p>	<p>Same</p>
<p>c) Coronal top design (Outer Features)</p>	<p>Same</p>	<p>Same</p>	<p>Same</p>	<p>Different</p>

Technological Characteristics	Proposed Device: GPS® Angled Abutment	Primary Predicate Device: GoDirect Implants (K090234 – Spectra System Dental Implants 2008)	Reference Predicate Device: Straight GPS Abutment (K143011 – 2014 InterActive/ SwishActive System)	Reference Predicate Device: InterActive® Swishplus2 Implant System (Abutment with Ball Top) (K130572 – InterActive/ SwishPlus2 Implant System)
d) Coronal top design (Internal Features)	Same	Same	Different	Different
e) Abutment Angle	15° and 30°	0°	0°	15° and 30°
f) Abutment / Implant Interface Type	Engaging	N/A	Non-engaging	Engaging
g) Attachment -Abutment Interface Platform	3.9mm	3.9mm	3.9mm	2.54mm
Material	Titanium alloy base with TiN coating	Titanium alloy base with TiN coronal surface	Titanium alloy base with TiN coating	Titanium alloy base
Sterilization:	Provided non-sterile with validated steam sterilization instructions for use. Product label indicates sterility according to ISO standard.	Provided sterile. No sterilization instructions needed for sterile product. Sterilization process is validated. Product label indicates sterility according to ISO standard.	Provided non-sterile with validated steam sterilization instructions for use. Product label indicates sterility according to ISO standard.	Provided non-sterile with validated steam sterilization instructions for use. Product label indicates sterility according to ISO standard.
Packaging	Mounted to inner vial, inside an outer vial and sealed with a cap	Mounted to inner vial, inside an outer vial and sealed with a cap	Mounted to inner vial, inside an outer vial and sealed with a cap	Mounted to inner vial, inside an outer vial and sealed with a cap

Non-Clinical Performance Data

Non-clinical testing was performed on the proposed GPS® Angled abutments.

Mechanical testing was performed on the proposed devices following FDA “Class II Special Control Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Abutments” and ISO 14801 in static compression and fatigue. The worst case abutment testing was performed on the proposed abutments with Implant Direct implants and with compatible third party implants. The implant/abutment device combinations were able to withstand an equivalent or higher load than the primary predicate device.

In addition, validations were conducted on non-sterile abutments for steam sterilization and biocompatibility testing.

A steam sterilization validation was conducted using the same sterilization parameters specified in the instructions for use which is used for the proposed devices. A sterilization validation was conducted on a non-sterile abutment conforming to AAMI/ANSI/ISO 17665-1 and ANSI/AAMI ST79 to a sterility assurance level (SAL) of 10^{-6} . In addition, the compatible GPS comfort cap was validated to be steam sterilizable.

Biocompatibility testing was conducted on the devices made with the same material and processes as the GPS components. Testing was conducted on the proposed Angled GPS Abutments, primary predicate GoDirect implant and compatible comfort caps according to ISO 10993-5. The results did not show a toxic reaction from the proposed finished devices.

The non-clinical performance data demonstrates that the proposed GPS® Angled abutments are mechanically equivalent, can be steam sterilized, and are biocompatible for the intended use.

Clinical Performance Data

[N/A]

Clinical data is not needed to adequately characterize substantial equivalence.

Conclusion as to Substantial Equivalence

The differences between the proposed devices and the predicate device were reviewed to evaluate the substantial equivalency. The following features are modifications to the primary predicate device.

- The proposed Angled GPS abutments are a multiple piece design using an angled abutment, fixation screw, and a GPS top to make the complete assembly. In comparison, the primary predicate GoDirect implant (K090234 – Spectra System Dental Implants 2008) is a solid

device where the coronal end of the implant is machined with GPS features. The coronal end of the GoDirect implant has the same features (including coating) as the GPS top (P/N: 1000-90S).

- The proposed Angled GPS abutments are manufactured at angles of 15° and 30°. The primary predicate device GPS top is straight and aligned with the implant axis.

The technical characteristics and non-clinical performance data demonstrate that the proposed GPS® Angled Abutments are substantially equivalent to the primary predicate device (GoDirect implant cleared under K090234 - Spectra System Dental Implants 2008).