DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 16, 2015

Implant Direct Sybron Manufacturing LLC
Ms. Ines Aravena
Sr. Director, Product Development and Regulatory Affairs
3050 East Hillcrest Drive
Thousand Oaks, California 91362

Re: K143011
Trade/Device Name: 2014 InterActive/SwishActive System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: June 18, 2015
Received: June 19, 2015

Dear Ms. Aravena,

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for Erin I. Keith, M.S.
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 STATEMENT

510(k) Number (if known): K143011

Device Name: 2014 InterActive/SwishActive System

Indications for Use:

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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY
for
2014 InterActive/SwishActive System

1. Submitter Information**:**

Company:	Implant Direct Sybron Manufacturing LLC
Address:	3050 East Hillcrest Drive, Thousand Oaks, CA 91362 USA
Contact Person:	Debleena Sinha
Telephone Number:	818-444-3306
Fax Number:	818-444-3406
Date Prepared:	July 16, 2015

2. Device Name:

- Proprietary Name: 2014 InterActive/SwishActive System
- Classification Name: Endosseous Dental Implant

- CFR Number: 872.3640
- Device Class: II
- Product Code: DZE and NHA

3. Predicate Device:

Primary Predicate
InterActive/SwishPlus2 Implant System (K130572)

Reference Predicate
NobelActive Internal Connection Implants (K071370)
NobelActive Zirconia Abutment (K072129)

4. Description of Device:

The 2014 InterActive/SwishActive System is a line extension of the previously cleared Implant Direct Sybron Manufacturing LLC, InterActive/SwishPlus2 Implant System (510K #130572) on December 24th, 2013). The name of the SwishPlus2 implants is changing to SwishActive and the Indications for Use within this submission has been revised from previous submission to only reflect the name change.

In addition, the previously cleared InterActive/SwishActive implants have been tested with NobelActive titanium 30 degree angled abutments to expand the indication for use as the test results show that the InterActive/SwishActive implants are prosthetically compatible with NobelActive NP (Narrow Platform – 3.0mm diameter) and NobelActive RP (Regular Platform – 3.4mm diameter) titanium abutments with up to 30 degree angulations.

Furthermore, the InterActive 30 degree abutments have been tested with NobelActive implants to expand the indication for use as the test results show that the InterActive abutments are prosthetically compatible with NobelActive NP (Narrow Platform – 3.0mm diameter) and NobelActive RP (Regular Platform – 3.4mm diameter) implants with up to 30 degree angulations.

Lastly, the 2014 InterActive/SwishActive System within this submission offers additional abutments that are intended to provide extra prosthetic options to the implant line. These abutments consist of two categories: (1) GPS straight abutments, and (2) Zirconia straight, angled, and modified Abutments.

GPS Straight Abutments

GPS abutments are used in attachment-retained, tissue supported restorations where the patient is fully or partially edentulous in the arch to be restored. These abutments are sold non-sterile with an accompanying *Instructions for Use* that provides clinicians with pre-use sterilization instructions. These abutments are made from Titanium 6AL-4V ELI with the coronal region having a Titanium Nitride (TiN) coating The TiN coating process was validated through cytotoxicty testing in accordance with ISO 10993-5.

The Straight GPS abutments are a one-piece design secured to the implant having identical interface features as the previously cleared InterActive Ball Abutments (**K130572**) These abutments are available in 1,2,3,4, 5 and 6mm in height.

Zirconia Straight, Angled, and Modified Abutments

Zirconia abutments are intended for use in partially or fully edentulous mandible and maxillae in support of single or multiple unit cement retained restorations. The abutments consist of two pieces, the titanium base and the zirconia top. The Zirconia abutments have identical interface features as the previously cleared

devices InterActive Cement Retained Abutments and Titanium Non-Engaging abutments (**K130572**). The abutments have a titanium base that has hex engaging and non-engaging implant/abutment interface having identical specifications as the previously cleared InterActive titanium abutments (**K130572**). The abutments have a coronal zirconia portion that is straight, angled, or it can be modified by the company to specific patient needs. The modifications to the top are restricted to minimal requirements: a maximum angle of 30° from the axis of the implant, a minimum wall thickness of 0.4mm, a minimum post height of 4mm, and a minimum cuff height from the interface of 0.7mm which are identical minimal requirements specified in the ***Instructions For Use*** for the previously cleared InterActive/SwishPlus2 abutments (**K130572**). These abutments are sold non-sterile with an accompanying ***Instructions for Use*** that provides clinicians with pre-use sterilization instructions.

5. Indications for Use:

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. 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.

6. Description of Substantial Equivalence:

Technological Characteristics

InterActive straight GPS abutments are one piece abutments with a apical threaded portion and coronal body that is compatible with InterActive and NobelActive implants. The coronal aspect of the InterActive abutments have similar external features as the NobelActive Locator abutments. Both abutments

are made from titanium and both have a titanium nitride coating. The technological characteristics table (TABLE 1) is shown below comparing the predicates to the proposed straight GPS abutments.

TABLE 1: Comparison between Predicate Devices and Proposed Devices - GPS Straight Abutments

Technological Characteristics	Primary Predicate Device: InterActive Ball Abutments (K130572)	Reference Predicate Device: NobelActive Locator Abutments (K071370)	Proposed Device: InterActive GPS Straight Abutments
Regulation No.	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630
Regulation Class	II	II	II
Product Code	NHA	NHA	NHA
Intended Use	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	Nobel Biocare's NobelActive implants are endosseous implant intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied.	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. 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

Technological Characteristics	Predicate Device: InterActive Ball Abutments (K130572)	Predicate Device: NobelActive Locator Abutments (K071370)	Proposed Device: InterActive GPS Straight Abutments
	NobelActive™ RP (Regular Platform – 3.4mm diameter) 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.		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.
General Design	Snap-on receiving cap attachment systems with thread engaging feature	Snap-on receiving cap attachment systems with thread engaging feature	Non-engaging straight abutments. Snap-on receiving cap attachment systems with thread engaging feature
Material	Titanium alloy	Titanium alloy with TiN surface	Titanium alloy with TiN surface
Attachment Connection	Ball Attachment	Locator Type Attachment	GPS/Locator Attachment
Implant/abut Interface	3.0 and 3.4 mm diameter interface	NP and RP interfaces	3.0 and 3.4 mm diameter interface
Packaging	Non-sterile inside a vial sealed with a cap	Non-sterile inside a vial sealed with a cap	Non-sterile inside a vial sealed with a cap

InterActive Zirconia abutments are two piece devices which have a titanium base with a anodized coating and coronal zirconia top which is provided as straight, angled, or modifiable according to patient needs. The apical portion of the InterActive abutments are compatible with NobelActive abutments. The coronal ziconia top is assembled to the titanium base and is made from a similar material as the NobelActive zirconia abutments. The NobelActive zirconia abutments are one piece abutments where the abutment body is made entirely from zirconia. The InterActive zirconia abutments differ from the NobelActive abutments by having a metalic titanium alloy base with a zirconia coronal top. The technological characteristics table (TABLE 2) is shown below comparing the predicates to the proposed zirconia abutments.

However, the differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate.

TABLE 2: Comparison between Predicate Devices and Proposed Devices - Zirconia Angled, Straight, Modified Abutments

Technological Characteristics	**Primary Predicate Devices: InterActive Straight Full Contour Abutments (K130572)**	**Reference Predicate Devices: NobelActive Titanium, Zirconia Abutments (K071370), (K072129)**	**Proposed Device: InterActive Zirconia Angled, Straight, Modified Abutments**
Regulation No.	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630
Regulation Class	II	II	II
Product Code	NHA	NHA	NHA
Intended Use	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 prosthetically compatible with Nobel Biocare conical connection NobelActive™ NP (Narrow Platform– 3.0mm diameter) and	Nobel Biocare's NobelActive implants are endosseous implant intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelActive implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. Nobel Biocare's NobelActive implants may be placed immediately and put into immediate function provided that initial stability requirements detailed in the manual are satisfied. The NobelActive Zirconia Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation in the anterior region.	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. 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

Technological Characteristics	Predicate Devices: InterActive Straight Full Contour Abutments (K130572)	Predicate Devices: NobelActive Titanium, Zirconia Abutments (K071370), (K072129)	Proposed Device: InterActive Zirconia Angled, Straight, Modified Abutments
	NobelActive™ RP (Regular Platform – 3.4mm diameter) (3.5-5.0mmD, 8.5-18mmLength) implants.		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.
General Design	One-piece abutment consisting of a engaging base, a straight body, and supplied with a fixation screw. The abutment body is straight and is contoured to match the gingival margin for cement retained prosthetics	One-piece abutment consisting of a titanium or Zirconia abutment that are pre-manufactured straight, angled or custom modified, and supplied with a fixation screw.	Two-piece abutment consisting of a titanium base, Zirconia abutment top that is straight, angled or modified up to 30 degrees, and supplied with a fixation screw.
Material	Titanium Alloy Base & Titanium Fixation Screw	Titanium Alloy or Zirconia body & Titanium Fixation Screw	Titanium Alloy Base, Zirconia Crown, & Titanium Fixation Screw
Implant/abut Interface	3.0 and 3.4 mm diameter interface	NP and RP interfaces	3.0 and 3.4 mm diameter interface
Packaging	Non-sterile inside a vial sealed with a cap	Non-sterile inside a vial sealed with a cap	Non-sterile inside a vial sealed with a cap

Non-Clinical Performance Data

Non-clinical testing was performed on InterActive implants and components. The testing is applicable for both proposed GPS and zirconia InterActive abutment types. Mechanical testing was performed according to ISO 14801 and was found to be equivalent to predicate device testing results. The following table (TABLE 3) gives a summary of the applicable testing.

TABLE 3: Summary of Fatigue performance data.

Proposed Devices	Applicable Testing	Testing	Summary	Result

Proposed Devices	Applicable Testing	Testing	Summary	Result
GPS Straight Abutments	InterActive Straight Titanium Abutment with Implant Direct Implant	Fatigue Testing according to ISO 14801	Proposed straight GPS abutments have an equivalent strength as the one piece straight abutments (K130572). The straight GPS abutments have an equivalent strength when assembled to Implant Direct implants(K130572).	Pass
GPS Straight Abutments	InterActive Straight Titanium Abutment with NobelActive Implant	Fatigue Testing according to ISO 14801	Straight GPS abutments have an equivalent or higher strength as the predicate abutment (K130572). The straight GPS abutments have an equivalent strength when assembled to NobelActive implants(K071370).	Pass
Straight, Angled, and Modified Zirconia Abutments	InterActive Modified Zirconia abutment with InterActive Implant	Fatigue Testing according to ISO 14801	The proposed zirconia abutment was tested and the results show it to be equivalent to the predicate abutment testing (K130572).	Pass

- Sterilization validation was conducted for the non-sterile components to ensure a SAL of 10-6. Sterilization validation was conducted according to FDA consensus standards ANSI/AAMI ST79 and ISO 17665-1/-2.
- Cytotoxicity testing was conducted according to ISO 10993-5 and -12 to demonstrate biocompatibility of the proposed device

Clinical Performance Data
[N/A]

Conclusion as to Substantial Equivalence

The differences between the proposed devices and the predicate devices were reviewed to evaluate the substantial equivalency. The following features are modifications to the cleared InterActive predicate abutment designs.

- GPS coronal top added to one-piece design.
- Zirconia top added to straight, angled abutments.
- Maximum of 30° angulation for Zirconia abutments when assembled to Implant Direct implants.
- Maximum of 30° angulation for Zirconia abutments when assembled to NobelActive implants.

The non-clinical testing results show the proposed abutments meet the device requirements and are equivalent to the predicate devices. The subject devices and the predicate device have the same intended use and have the same technological characteristics.