DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 15, 2017

Dentsply Sirona
Helen Lewis
Director Corporate Regulatory Affairs
221 West Philadelphia Street
Suite 60W
York, Pennsylvania 17401

Re: K170849
Trade/Device Name: SIMPLANT® Guide
Regulation Number: 21 CFR 872.3980
Regulation Name: Endosseous Dental Implant Accessories
Regulatory Class: Class I
Product Code: NDP
Dated: March 21, 2017
Received: March 22, 2017

Dear Helen Lewis:

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,

Andrew I. Steen -S

for Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170849

Device Name
SIMPLANT® Guide

Indications for Use *(Describe)*

The SIMPLANT® Guide is intended for use in assisting placement of dental 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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SECTION 5. 510(k) SUMMARY
for
SIMPLANT® Guide K170849

Submitter Information**:**

Dentsply Sirona
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Suite 60W
York, PA 17401

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
Fax Number: 717-849-4343

Date Prepared: June 14, 2017

Device Name:

- Proprietary Name: SIMPLANT® Guide
- Classification Name: Endosseous dental implant accessories
- CFR Number: 872.3980
- Device Class: Class I
- Product Code: NDP

Predicate Device:

Predicate Device Names	510(k)	Manufacturer
SimPlant® Immediate Smile System (Primary Predicate)	K113739	DENTSPLY Implants NV
Frialit-2 Select Components (Reference Predicate)	K993095	Dentsply Implants Manufacturing GmbH
FRIALIT-2 Bone Profiler (Reference Predicate)	K993560	Dentsply Implants Manufacturing GmbH

Description of Device:

The SIMPLANT® Guide is intended for use in assisting placement of dental implants.

It is a patient specific surgical template that is produced based upon knowledge of the location and orientation of the implant(s) prior to the surgery.

The design of the SIMPLANT® Guide is made according to the clinician's plan of the implant positions. The final guide is fabricated from an epoxy resin using computer-assisted manufacturing to produce a patient specific device.

The SIMPLANT® Guide sits on the patient's oral anatomy, i.e. teeth, mucosa, bone or a combination thereof. Aided by the SIMPLANT® Guide, the implant sites can be prepared and the dental implants placed in the predetermined locations.

Indications for Use:
The SIMPLANT® Guide is intended for use in assisting placement of dental implants.

Substantial Equivalence:

Dentsply Sirona received premarket clearance for the primary predicate SimPlant® Immediate Smile System in May 2012 under premarket notification K113739. The primary predicate, SimPlant® Immediate Smile System (K113739), is composed of the SimPlant® Immediate Smile bridge, SurgiGuide® guide and SimPlant® Software.

Dentsply Sirona modified the SurgiGuide® guide, component of the SimPlant® Immediate Smile System (K113739). This modified SurgiGuide® guide is herewith submitted as a new 510(k) under the name SIMPLANT® Guide.

The revision to the SurgiGuide® guide relates to the use of a different acrylic epoxy resin for the body of the guide. In addition, a reduced wall thickness of the body of the guide is introduced and the shelf life has been changed. Finally, the recommended sterilization parameters are updated as described in the Instructions For Use.

This modified SurgiGuide® guide is herewith submitted as new 510(k) under the name SIMPLANT® Guide.

Table 5.1 shows the similarities and differences between the SIMPLANT® Guide and the SurgiGuide® guide, component of the primary predicate SimPlant® Immediate Smile System (K113739). Throughout this submission we will compare the SIMPLANT® Guide with the SurgiGuide® guide.

Table 5.1 Substantial Equivalence Table

Element	Proposed Device SIMPLANT® Guide (K170849)	Primary Predicate Device SimPlant® Immediate Smile System (K113739)	Similarities and Differences
Indications for Use	The SIMPLANT® Guide is intended for use in assisting placement of dental implants.	The SimPlant® Immediate Smile System is intended for use in treatment planning and placement of dental implants, in order to restore masticatory function.	The indications for use of the proposed SIMPLANT® Guide are limited to the indications for use of the guide only.
Function	The SIMPLANT® Guide is a patient-specific surgical template that is produced based upon knowledge of the location and orientation of the implant(s) prior to the surgery. Aided by the SIMPLANT® Guide, the sites can be prepared and the implants placed in the predetermined locations.	The SimPlant® Immediate Smile System includes SimPlant® software, which provides a means for the clinician for image segmentation and advanced pre-operative planning. This enables the clinician to view three-dimensional CT-scan data as well as to plan the case in a virtual three-dimensional environment. This case planning can be used to produce a surgical template, this transferring the virtual case planning into physical tools enabling the surgical installation according to the virtual case planning. The SurgiGuide® guide is a patient-specific surgical template that is produced based upon knowledge of the location and orientation of the implant(s) prior to the surgery. Aided by the SurgiGuide® guide, the sites can be prepared and the implants placed in the predetermined locations. After placing the implants in the predetermined locations, the immediate attachment of the prefabricated temporary prosthesis, i.e. the Immediate Smile bridge structure or final prosthesis is possible.	The function of the proposed SIMPLANT® Guide is identical to the function of the SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739).

Element	Proposed Device SIMPLANT® Guide (K170849)	Primary Predicate Device SimPlant® Immediate Smile System (K113739)	Similarities and Differences
Technology	• Stereolithography	SurgiGuide® guide: • Stereolithography	The technology of the proposed SIMPLANT® Guide is identical to the technology of the SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739).
Material	• Acrylic epoxy resin • Glue • Medical grade metal tubes (stainless steel or Titanium)	SurgiGuide® guide • Acrylic epoxy resin • Glue • Medical grade metal tubes (stainless steel or Titanium)	The raw material used for the body of the guide is different for the proposed SIMPLANT® Guide as compared to the SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739). A different acrylic epoxy resin is used. Other materials used in the proposed SIMPLANT® Guide are identical to the materials used in the SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739).
Design and Features	• Patient specific surgical template that sits on the patient's oral anatomy, i.e. teeth, mucosa or bone • Minimal wall thickness: 2.5 mm • Metal tubes with position and dimensions based on the pre-operative plan	SurgiGuide® guide: • Patient specific surgical template that sits on the patient's oral anatomy, i.e. teeth, mucosa or bone • Minimal wall thickness: 3mm • Metal tubes with position and dimension based on the pre-operative plan	The design specification of the minimal wall thickness is different for the proposed SIMPLANT® Guide as compared to the SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739). All other design aspects and features of the proposed SIMPLANT® Guide are identical to the design aspects and features of the SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739).
Sterilization Method	• Delivered non-sterile • Sterilization by the user: Steam-sterilization at 135°C / 275°F for 3 minutes and a minimal drying time of 16 minutes	SurgiGuide® guide: • Delivered non-sterile • Sterilization by the user: Steam-sterilization at 121°C for 20 minutes	The sterilization method of the proposed SIMPLANT® Guide is identical to the sterilization method of the SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739). However, the sterilization cycle parameters are different.

Element	Proposed Device SIMPLANT® Guide (K170849)	Primary Predicate Device SimPlant® Immediate Smile System (K113739)	Similarities and Differences
Shelf Life	• 2 months	SurgiGuide® guide: • 6 months	The shelf life of the proposed SIMPLANT® Guide is reduced compared to the shelf life of the SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739).

The SIMPLANT Guide has similar uses as the reference predicate devices, FRIALIT-2 Select Components (K993095) and FRIALIT-2 Bone Profiler (K993560). The reference predicate, FRIALIT-2 Select Components (K993095) are used to determine available tissue height, implant site angle and abutment angle. The reference predicate, FRIALIT-2 Bone Profiler (K993560) consists of a stainless steel drill and a drill guide. A drill guide is provided with each diameter drill to aid in the determination of implant angle and implant depth to facilitate removal of bone around the implant site. These reference devices were cleared under DZE prior to announcement in 65 FR 60099 of reclassification of dental implant accessories under 872.3980 Endosseous dental implant accessories and product code NDP.

Non-Clinical Performance Data

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include data from the following tests:

Bench Testing

For the proposed SIMPLANT® Guide, non-clinical performance tests have been developed in-house including their related acceptance criteria and were executed to demonstrate substantial equivalence. Table 5.1 gives an overview of these tests and the results that are obtained, when tested against the acceptance criteria. All tests met the acceptance criteria.

The fixation and bending test results show that the proposed SIMPLANT® Guide has sufficient strength for its intended use. The results from the angulation deviation test, position deviation test and vertical fit test demonstrate that the SIMPLANT® Guide is manufactured according to its pre-operative plan. The performance of the SIMPLANT® Guide meets the same acceptance criteria for all bench tests, as compared to the SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739).

Table 5.2 Performance testing

Bench Test Performed	Test description	Result for Proposed SIMPLANT® Guide (PASS / FAIL)	Result for SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739) (PASS / FAIL)
Tube Fixation Test-Push Out	This test is executed to ensure that the proposed device withstands typical vertical loads that may be applied during surgery.	PASS	PASS
Tube Fixation Test-Torque	This test is executed to ensure that the proposed device withstands occasional torque loads that may be applied during surgery.	PASS	PASS
Bending Test	This test is executed to ensure that the proposed device withstands typical bending loads that may be applied during surgery	PASS	PASS
Angulation Deviation Test	The deviation is measured between the angulation of the metal tube of the designed and the manufactured guide. This test is executed to ensure that the proposed SIMPLANT® Guide is manufactured according to its pre-operative plan regarding the angular position of the guiding tube.	PASS	PASS
Position Deviation Test	This test is executed to ensure that the proposed SIMPLANT® Guide is manufactured according to its pre-operative plan regarding spatial position of the guiding tube.	PASS	PASS
Vertical Fit Test	This test is executed to ensure that the proposed SIMPLANT® Guide is manufactured according to its pre-operative plan regarding the vertical position.	PASS	PASS

Biocompatibility Testing

A biocompatibility assessment and relevant testing, based on the requirements of ISO 10993-1 (2009, Cor 1:2010) *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process* and 7405 (2008) *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry* was performed on the proposed SIMPLANT® Guide.

Following tests for biocompatibility were performed:

- Cytotoxicity test, in accordance to ISO 10993-5 (2009) *"Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity"*
- Intracutaneous reactivity test , in accordance to ISO 10993-10(2010) "*Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization"*
- Sensitization test , in accordance to ISO 10993-10(2010) "*Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization"*

These tests demonstrated the biocompatibility of the proposed SIMPLANT® Guide.

Sterilization Validation

The steam-sterilization method for the proposed SIMPLANT® Guide is stated in the Instructions For Use of the SIMPLANT® Guide. The steam-sterilization method for the SIMPLANT® Guide is similar to the steam-sterilization method of the SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739), but has modified sterilization cycle parameters. The updated steam-sterilization method has been successfully validated according to ISO 17665-1 (2006) *"Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices"* and ISO 17665-2 (2009) *"Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1."*

Shelf life testing

The shelf life of the proposed SIMPLANT® Guide is 2 months. To ensure the stability and performance of the proposed SIMPLANT® Guide through the claimed shelf life, relevant shelf life testing was performed based on real-time aging. These tests include:

- Tube Fixation Test-Torque
- Bending test
- Vertical fit test

The performance of the SIMPLANT® Guide after real-time ageing for 2 months meets the same acceptance criteria as for the bench tests performed at the time of manufacture.

The proposed SIMPLANT® Guide satisfactorily met the requirements of the non-clinical performance testing conducted to support substantial equivalence.

Clinical Performance Data

No new data from human clinical studies has been included to support the substantial equivalence to the SimPlant® Immediate Smile System (K113739). The clinical data from the previously cleared SurgiGuide® guide, component of SimPlant® Immediate Smile System (K113739) are still valid for the SIMPLANT® Guide, since the clinical indication and performance of both devices are the same.

Conclusion Regarding Substantial Equivalence

The SIMPLANT® Guide has the same indication for use, incorporates the same fundamental product technology and similar materials as the SurgiGuide® guide, component of the primary predicate SimPlant® Immediate Smile System (K113739). Bench testing shows that performance of the proposed SIMPLANT® Guide meets the same performance acceptance criteria as the primary predicate, SurgiGuide® guide, component of SimPlant® Immediate Smile System (K113739). New biocompatibility testing was successfully performed according ISO 10993-5 (2009), ISO 10993-10 (2010). Shelf life tests confirmed the proposed shelf life of 2 months. Finally, the updated recommended steam-sterilization method was successfully validated according to ISO 17665-1(2006) and ISO 17665-2(2009). These results support substantial equivalence of the proposed device SIMPLANT® Guide to the primary predicate device SurgiGuide® guide, component of the predicate SimPlant® Immediate Smile System (K113739). Any differences in technological characteristics between the proposed device and the primary predicate device do not raise different questions of substantial equivalence.