September 2, 2020

Dentsply Sirona
Karl Nittinger
Vice President Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K193405
Trade/Device Name: Simplant® Digital Guide
Regulation Number: 21 CFR 872.3980
Regulation Name: Endosseous Dental Implant Accessories
Regulatory Class: Class I
Product Code: NDP
Dated: July 30, 2020
Received: July 31, 2020

Dear Karl Nittinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193405

Device Name
Simplant® Digital Guide

Indications for Use *(Describe)*
The Simplant® Digital Guide is a surgical guide intended for use in assisting in the placement of dental implants. The Simplant® Digital Guide is designed centrally by the Simplant® planning software and manufactured locally using Formlabs Dental SG resin, Loctite 4304 adhesive, and Formlabs equipment: Form 2 printer, FormWash and FormCure washing and post-curing equipment.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401

510(k) SUMMARY
for K193405
Simplant® Digital Guide

Submitter Information:

Dentsply Sirona

221 West Philadelphia Street
Suite 60W
York, PA 17401

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343
Email: karl.nittinger@dentsplysirona.com

Date Prepared: 02-September-2020

Device Name:

- Proprietary Name: Simplant® Digital Guide
- Classification Name: Endosseous Dental Implant Accessories
- CFR Number: 21 CFR 872.3980
- Device Class: Class I
- Product Code: NDP

Predicate Device:

Predicate Device Name	510(k)	Company Name
Simplant® Guide	K170849	Dentsply Sirona

Description of Device:

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

The subject Simplant® Digital Guide is a patient specific surgical template, which is designed according to the digital pre-operative plan of the dental implant positions. The clinician, or dental lab, orders a digital design file of the surgical guide (i.e. Simplant® Guide File) which is developed under the same process that is utilized to produce the design of the predicate Simplant® Guide (K170849). The subject Simplant® Digital Guide is then fabricated locally by the clinician or dental lab, utilizing stereolithography fabrication method. The subject Simplant® Digital Guide is intended to be fabricated using Dental SG acrylic resin, Form 2 SLA 3D printer, and FormWash and FormCure washing and post-curing equipment manufactured by Formlabs, Inc.

The Simplant® Digital Guide sits on the patient's oral anatomy, i.e. teeth, mucosa or combination thereof. Aided by the Simplant® Digital Guide, the implant sites can be prepared, and the dental implants can be placed in the predetermined locations according to the previously pre-operative dental implant treatment plan.

Indications for Use:

The Simplant® Digital Guide is a surgical guide intended for use in assisting in the placement of dental implants. The Simplant® Digital Guide is designed centrally by the Simplant® planning software and manufactured locally using Formlabs Dental SG resin, Loctite 4304 adhesive, and Formlabs equipment: Form 2 printer, FormWash and FormCure washing and post-curing equipment.

Substantial Equivalence:

Technological Characteristics.

An overview of the similarities and differences between the subject and predicate devices are given in Table 5.1.

Table 5.1-Similarities and Differences			
Element	**Subject Device** **Simplant® Digital Guide**	**Predicate Device** **Simplant® Guide** **(K170849)**	**Similarities and Differences**
Indications for Use	The Simplant® Digital Guide is a surgical guide intended for use in assisting in the placement of dental implants. The Simplant® Digital Guide is designed centrally by the Simplant® planning software and manufactured locally using Formlabs Dental SG resin, Loctite 4304 adhesive, and Formlabs equipment: Form 2 printer, FormWash and FormCure washing and post-curing equipment.	The Simplant® Guide is intended for use in assisting placement of dental implants.	Both the subject Simplant® Digital Guide and predicate Simplant® Guide (K170849) are intended for use in assisting placement of dental implants. However, predicate Simplant® Guide (K170849) is fabricated locally by Dentsply Sirona and subject Simplant® Digital Guide is fabricated locally by the clinician or dental lab.
Function and Principle of Operation	• Supporting surface: teeth and mucosa • Function: Guidance of instruments according to pre-operative plan • Surgical procedure: Sequence of instruments according to manufacturer's instructions.	• Supporting surface: teeth, mucosa and bone • Function: Guidance of instruments according to pre-operative plan • Surgical procedure: Sequence of instruments according to manufacturer's instructions.	The function and principle of operation of the subject Simplant® Digital Guide are almost identical to the function and principle of operation of the predicate Simplant® Guide (K170849). The subject Simplant® Digital Guide is limited to seating on teeth, mucosa and combination thereof. Predicate Simplant® Guide (K170849) can also be seated directly on the bone. The fabrication process of subject Simplant® Digital Guide is not adapted to fabrication of bone models, which are needed for quality control verification of bone supported surgical guides. Therefore, subject Simplant® Digital Guide is not intended as a bone supported variant.

Element	**Subject Device** **Simplant® Digital Guide**	**Predicate Device** **Simplant® Guide**	**Similarities and Differences**
Technology	Guide design by Dentsply Sirona or by clinician and review by Dentsply Sirona. Local fabrication by stereolithography. • Print: - Software: PreForm (manufacturer: Formlabs) - Equipment: Form 2 (manufacturer: Formlabs) • Wash: Equipment: Form Wash (manufacturer: Formlabs) • Post-cure: Equipment: Form Cure (manufacturer: Formlabs)	Guide design by Dentsply Sirona or by clinician and review by Dentsply Sirona. Internal (Dentsply Sirona) fabrication by stereolithography.	The design process for the subject Simplant® Digital Guide and predicate Simplant® Guide (K170849) are the same. The technology applied to create the subject Simplant® Digital Guide is different from predicate Simplant® Guide (K170849). Both subject and predicate device are created by stereolithography, however, the fabrication of predicate Simplant® Guide (K170849) is executed centrally by Dentsply Sirona and the fabrication of subject Simplant® Digital Guide is performed locally by the clinician or lab utilizing the Formlabs printer and acrylic resin. Bench and performance testing is included to address technological differences between the subject and predicate device in support of substantial equivalence.
Material	• Body: Acrylic resin: Dental SG (manufacturer: Formlabs) • Metal tube/sleeve: Titanium alloy • Adhesive: Loctite 4304	• Body: Acrylic resin • Metal tube/sleeve: Titanium alloy or stainless steel • Adhesive	The material composition of the subject Simplant® Digital Guide is different than that of the predicate Simplant® Guide (K170849). While both are fabricated from acrylic resin in an additive manufacturing process, a different specific acrylic resin is used for the subject device. The material for tubes/sleeves is limited to titanium alloy and the glue is the same. Assessment of the biocompatibility of the subject device is included to address the material and process differences between the subject and predicate device in support of substantial equivalence.

Element	**Subject Device** **Simplant® Digital Guide**	**Predicate Device** **Simplant® Guide** **(K170849)**	**Similarities and Differences**
Design and Features	• Body: - Surface following - Wall thickness: minimum 2.5 mm • Metal tube/sleeve: Dimensions and position depending on pre-operative plan	• Body: - Surface following - Wall thickness: minimum 2.5 mm • Metal tube/sleeve: Dimensions and position depending on pre-operative plan	The fundamental design parameters and metal tubes of the subject Simplant® Digital Guide are identical as compared to predicate Simplant® Guide (K170849).
Sterilization Method	Sterilization by the user:	Sterilization by the user:	The sterilization method is the same. .
Shelf Life	2 weeks	2 months	The shelf life of the subject Simplant® Digital Guide is reduced as compared to predicate Simplant® Guide (K170849). This difference is supported by the fact that the local manufacture of the subject device lends itself to use of the device within a short time period after fabrication.

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:

- Tube fixation test – push out.

This test is executed to ensure that the subject device withstands typical vertical loads that may be applied during surgery.

- Tube fixation test – torque.

This test is executed to ensure that the subject device withstands occasional torque loads that may be applied during surgery.

- Strength test.

This test is executed to ensure that the subject device complies with the international standard related to dental materials, ISO 20795-1:2013-1 Dentistry - Base polymers - Part 1: Denture base polymers.

- Angulation deviation test.

This test is executed to ensure that the subject device is manufactured according to its pre-operative plan regarding the angular position of the guide sleeve.

- Position deviation test.

This test is executed to ensure that the subject device is manufactured according to its pre-operative plan regarding the spatial position of the guide sleeve.

- Vertical fit test.

This test is executed to ensure that the subject device is manufactured according to its pre-operative plan regarding the vertical position. As a result of the angulation deviation test, the centrally controlled (by Dentsply Sirona) design process is updated. For the subject device the safety margin between the planned implant and the lingual bone plate is slightly increased.

Development of bench testing to support the assessment of the additive manufacturing process variables was conducted with reference to the December, 2017 Guidance for Industry and Food and Drug Administration Staff: *Technical Considerations for Additive Manufactured Medical Devices*.

- The additive manufacturing process workflow was validated considering the critical additive manufacturing process variables that could affect the final product specifications. Considerations for build location, build orientation, print layer thickness, and potential for raw material reuse were made. Strength test, tube fixation (pushout and torque), angulation deviation, position deviation, and vertical fit tests were conducted on samples from at least 3 build runs to confirm that the process variables do not affect the finished device's conformance to its predetermined specifications.

Biocompatibility Testing:

Biocompatibility assessment and relevant testing based on the requirements of *ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and *ISO 7405:2008 Dentistry - Evaluation of biocompatibility of medical devices used in dentistry* was performed for the subject Simplant® Digital Guide. It is concluded that the subject Simplant® Digital Guide meets the criteria for biocompatibility according to these standards.

Sterilization Validation:

The updated steam sterilization parameters were 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* demonstrating a sterility assurance level (SAL) of 10^{-6}.

Shelf Life Testing:

The shelf life of the subject Simplant® Digital Guide is 2 weeks. To ensure the performance of subject Simplant® Digital through the claimed shelf life, all the performed bench testing on subject device was executed on samples that were sterilized and subjected to real-time aging for 2 weeks.

The results from the non-clinical performance testing, in combination with an updated design process, support substantial equivalence of the subject device Simplant® Digital Guide to the predicate device Simplant® Guide (K170849).

Clinical Performance Data.

No data from human clinical studies has been included to support the substantial equivalence of the Simplant® Digital Guide.

Conclusion Regarding Substantial Equivalence

The subject Simplant® Digital Guide is a patient specific surgical template which is intended for use in assisting placement of dental implants. The Simplant® Digital Guide has identical Indications for Use, exhibits identical fundamental design features and similar principles of operation as the predicate Simplant® Guide cleared under premarket notification K170849. Test data to verify the performance of the Simplant® Digital Guide has been included. The results of this testing, and the comparison with the predicate device, support substantial equivalence.