September 27, 2019

Dentsply Sirona
Karl Nittinger
Director, Corporate Regulatory Affairs
221 West Philadelphia St., Suite 60W
York, Pennsylvania 17401

Re: K190059
Trade/Device Name: CEREC Guides
Regulation Number: 21 CFR 872.3980
Regulation Name: Endosseous Dental Implant Accessories
Regulatory Class: Class I
Product Code: NDP
Dated: June 28, 2019
Received: July 1, 2019

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.
Acting Division 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)*

K190059

Device Name

CEREC Guides

Indications for Use *(Describe)*

CEREC Guides are intended to support the dentist or oral surgeon when drilling for placement of dental implants. CEREC Guides are intended to be designed and fabricated using the Sirona Dental CAD/CAM System's CEREC Chairside software and CAM equipment, Galileos Implant dental implant planning software, and Calibra Universal Self-Adhesive Resin Cement.

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

K190059: 510(k) SUMMARY
CEREC Guides

1. 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

Date Prepared: 27-September-2019

2. Device Name:

- Proprietary Name: CEREC Guides
- Classification Name: Endosseous dental implant accessories.
- CFR Number: 21 CFR 872.3980
- Device Class: Class I
- Product Code: NDP (*Accessories, Implant Dental, Endosseous*)

3. Predicate and Reference Devices:

The predicate device that has been identified relating to the substantial equivalence of the CEREC Guides is:

Predicate Device	**510(k) Clearance**	**Company Name**
SIMPLANT Guide	K170849	Dentsply Sirona

Reference Devices:

Reference Device	510(k) Clearance	Manufacturer
Sirona Dental CAD/CAM System	K181520	Dentsply Sirona
Galileos Implant (dental implant planning software)	K093090	SICAT GmbH & Co. KG
Calibra Univeral Self-Adhesive Resin Cement	K073173	Dentsply Sirona
Weiland Zeno CAO Temporary PMMA Disc	K071548	Merz Dental GmbH

4. Description of Device:

The CEREC Guide dental surgical guides are milled poly(methyl methacrylate) [PMMA] devices which are designed and fabricated utilizing the Sirona Dental CAD/CAM System with CEREC Chairside Software (K181520) and are intended to act only as dental implant placement templates. The CEREC Guides are designed in the Sirona Dental CAD/CAM System's CEREC Chairside Software utilizing, as an input, a completed dental implant treatment plan which is developed in the "Galileos Implant" dental implant treatment planning software as cleared under premarket notification K093090.

The CEREC Guide surgical guides are offered in two variants, the CEREC Guide 2 and CEREC Guide 3. Both the CEREC Guide 2 and CEREC Guide 3 are milled from the CEREC Guide Bloc milling blocks. The CEREC Guide Blocs are clear, PMMA blocks intended for milling utilizing the CEREC MC XL family of milling units. CEREC Guide Blocs are offered in two size variants, "medi" and "maxi".

The CEREC Guide 2 surgical guides consist of the surgical guide body milled from the CEREC Guide Bloc PMMA milling blocks. The CEREC Guide 2 surgical guides are used in conjunction with CEREC Guide Drill Keys. CEREC Guide Drill Keys are stainless steel, reusable drill guide instruments which are offered in variants with internal diameters ranging from 2.0 mm to 4.85 mm.

The CEREC Guide 3 surgical guides consist of the CAD/CAM surgical guide body milled from the CEREC Guide Bloc PMMA milling blocks. CEREC Guide 3 surgical guides feature integral titanium guide sleeves that are bonded the CEREC Guide 3 surgical guide body using Dentsply Sirona Calibra® Universal adhesive (K073173). The CEREC Guide 3 Guide Sleeves are single use and are offered in 4 size variants, with outer diameters ranging from 5.5 mm to 6.0 mm, and internal diameters ranging from 4.48 mm – 5.2 mm.

5. Indications for Use:

CEREC Guides are intended to support the dentist or oral surgeon when drilling for placement of dental implants. CEREC Guides are intended to be designed and fabricated using the Sirona Dental CAD/CAM System's CEREC Chairside software and CAM equipment, Galileos Implant dental implant planning software, and Calibra Universal Self-Adhesive Resin Cement.

6. Substantial Equivalence:

The CEREC Guide has the same intended use and incorporate the same fundamental technology as the predicate SIMPLANT Guide cleared under premarket notification K170849. The indications for use of the subject CEREC Guides in comparison to the indications for use of the predicate SIMPLANT Guide (K170849) references the CEREC Guide design and fabrication functionality using the Sirona Dental CAD/CAM System's (K181520) CEREC Chairside software and CAM equipment as well as the other system components.

Summary comparison of the intended use, indications for use, and features of the subject CEREC Guides with those of the predicate SIMPLANT Guide cleared under K170849 is presented in Tables 6.1 and 6.2.

Table 6.1: Indications for Use

Subject Device **CEREC Guides**	**Predicate Device** **SIMPLANT Guide (K170849)**
Indications for Use	
CEREC Guides are intended to support the dentist or oral surgeon when drilling for placement of dental implants. CEREC Guides are intended to be designed and fabricated using the Sirona Dental CAD/CAM System's CEREC Chairside software and CAM equipment, Galileos Implant dental implant planning software, and Calibra Universal Self-Adhesive Resin Cement.	The SIMPLANT Guide is intended for use in assisting placement of dental implants.

The indications for use of the CEREC Guides as subject to this premarket notification include identification of the reference devices which are utilized in the chairside design and fabrication of the subject devices and are listed in support of substantial equivalence. The intended use of the reference devices [Sirona Dental CAD/CAM System with CEREC Chairside Software (K181520), Galileos Implant dental implant treatment planning software (K093090), and Calibra Universal Self-Adhesive Resin Cement (K073173)] include the design and fabrication of dental prosthetic restorations and CAD/CAM dental abutments, the planning of oral surgery, and restorative dental procedures, respectively. The specific differences related to the intended use of the subject device as compared to the reference devices was mitigated by bench testing.

Table 6.2: Design

Subject Device **CEREC Guides**	**Predicate Device** **SIMPLANT Guide** **(K170849)**	**Similarities** **And** **Differences**
Technology		
Chairside CAD/CAM design and milling.	Internal design and fabrication by stereolithography.	The subject CEREC Guides are designed and fabricated by the clinician using CAD/CAM design and milling at chairside while the predicate device (K170849) is designed in consultation with the clinician and fabricated by stereolithography methods in an internal manufacturing environment. The technological differences are mitigated by bench testing included in support of substantial equivalence.
Material		
- Poly(methyl methacrylate) acrylic millable block. - Calibra Universal Self-Adhesive Resin Cement. - Integral titanium drill guide sleeves.	- Acrylic epoxy resin. - Medical grade adhesive. - Titanium or stainless steel drill guide sleeves.	The subject CEREC Guides are fabricated by milling from solid poly(methyl methacrylate) acrylic blocks while the predicated device (K170849) are manufactured by stereolithography and composed of acrylic epoxy resin. The particular material formulation differences between the subject device and the predicate device (K170849) are mitigated by biocompatibility testing included in support of substantial equivalence.

Table 6.2: Design (continued)

Subject Device **CEREC Guides**	**Predicate Device** **SIMPLANT Guide** **(K170849)**	**Similarities** **And** **Differences**
Design and Features		
- Patient-specific dental implant placement template. - Minimal wall thickness: 1 mm - Integral metallic (titanium) guide sleeves with position and dimensions based on the clinician's pre-operative dental implant treatment plan.	- Patient-specific dental implant placement template. - Minimal wall thickness: 2.5 mm - Integral metallic (titanium or stainless steel) guide sleeves with position and dimensions based on the clinician's pre-operative dental implant treatment plan.	The design features of the subject CEREC Guides are similar to those of the predicate device (K170849). Both are patent-specific devices whose design is finalized according to the clinician's pre-operative treatment plan. The specific design differences between the subject device and the predicate device (K170849) are mitigated by bench testing included in support of substantial equivalence.
Sterilization / Disinfection Method		
- Fabricated by the clinician and are non-sterile when completed. - Single-use devices processed via high-level disinfection by the end user clinician prior to initial use.	- Delivered non-sterile to the clinician. - Single-use devices processed via steam sterilization by the end user clinician prior to initial use.	The subject and predicate (K170849) devices are either "finalized" (fabricated by the clinician at chairside in the case of the subject device or delivered from the manufacturer to the clinician in the case of the predicate device) in a non-sterile state and must be processed by the end user prior to clinical use. The differences in the specific method for pre-operative processing of the subject and predicate (K170849) devices are mitigated by validation testing included in support of substantial equivalence.

7. Non-Clinical Performance Data

Testing to verify the performance requirements of the subject CEREC Guides was conducted and included in this premarket notification. The results of the performance testing support substantial equivalence.

Tests included in this premarket notification:

- Validation of the device's software, including input data from Galileos Implant and calibration of the compatible milling unit, in conformity with IEC 62304 (*Medical device software – Software lifecycle processes*) and with deliverables compiled and included with reference to *Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions of Software Contained in Medical Devices* (May, 2005).
- Validation testing conducted to confirm the accuracy of the milled CEREC Guide devices comparing the CEREC SW surgical guide design with respect to deviation of the apical position of the drill with the apical position determined from the implant treatment plan developed using the Galileos Implant dental implant planning software.
- Material strength analysis based on the requirements of ISO 10477 (*Dentistry – Polymer-based crown and bridge veneering materials*), published clinical literature referencing forces applied during intra-oral surgical drilling and bite forces, and the PMMA material characteristics of the subject CEREC Guides and the PMMA reference devices.
- Bench test data supporting the requirement that the force required to push out the bonded CEREC Guide 3 drill sleeve exceeds the intra-surgical drilling forces that have been reported in published literature.
- Biocompatibility testing on the CEREC Guide Bloc PMMA material and on the finished CEREC Guide 3 (incorporating the CEREC Guide Bloc PMMA material, the Guide Sleeves, and the Calibra® Universal adhesive). Biocompatibility evaluation and testing were conducted with reference to the June, 2016, CDRH Guidance for Industry and Food and Drug Administration Staff: *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".*
- Validation of the high-level disinfection process which is recommended for the single-use CEREC Guides prior to their use was conducted with reference to the March, 2015 CDRH/CBER Guidance for Industry and Food and Drug Administration Staff: *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.*

8. Clinical Performance Data

No human clinical data was included in this premarket notification to support the substantial equivalence of the subject CEREC Guides.

9. Conclusion Regarding Substantial Equivalence

The information included in this premarket notification supports the substantial equivalence of the subject CEREC Guides. The subject CEREC Guides have the same intended use as the legally marketed predicate device cleared under premarket notification K170849. The subject device also has similar indications for use and incorporates the same fundamental technology as the predicate device (K170849).

Performance data, software integration deliverables, and analyses are included in this premarket notification to verify the design, functionality, and safety requirements of CEREC Guides. The results of the testing included in this premarket notification support a determination of substantial equivalence.