January 11, 2018

Dentsply Sirona
Karl J. Nittinger
Senior Manager & Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60W
York, Pennsylvania 17401

Re: K171122
Trade/Device Name: CEREC Ortho Software
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: December 11, 2017
Received: December 13, 2017

Dear Karl J. 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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For
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

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)*

K171122

Device Name

CEREC Ortho Software

Indications for Use *(Describe)*

CEREC Ortho Software is intended for use with image data acquired from handheld intra oral 3D cameras and desktop laboratory scanners to create 3D virtual models to be used for data acquisition and modeling analysis for orthodontic patients and conditions. The CEREC Ortho Software 3D model data can be exported to orthodontic design software to aid in the design of orthodontic appliances.

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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SECTION 5.
510(k) SUMMARY
K171122
CEREC Ortho Software

1. Submitter Information**:**

Dentsply Sirona
221 West Philadelphia Street
Suite 60
York, PA 17404

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
Fax Number: 717-849-4343

Date Prepared: January 5, 2018

2. Device Name:

- Proprietary Name: CEREC Ortho Software
- Classification Regulation Name: Orthodontic plastic bracket.
- CFR Number: 21 CFR 872.5470
- Device Class: Class II
- Product Code: PNN (*Orthodontic Software*)

3. Predicate Device:

The predicate device for the CEREC Ortho Software is:

Predicate Device Name	**510(k)**	**Company Name**
3Shape Ortho System™	K152086	3Shape A/S

4. Description of Device:

The CEREC Ortho Software is stand-alone software which utilizes images of the patient's intra-oral anatomy from intra-oral cameras and/or desktop laboratory scanners to create a 3D virtual dental model that can be used in the same manner as a traditional physical dental model.

The CEREC Ortho Software facilitates the segmentation and editing of the 3D virtual digital model as well as analysis which can be used in secondary orthodontic treatment planning. The software allows for measurement and jaw analysis to be performed – including Bolton, Nance, and Moyers analyses. The models and analysis produced by the proposed CEREC Ortho Software can be exported to an orthodontic laboratory or directly to orthodontic appliance manufacturers for use in orthodontic treatment planning and design of orthodontic appliances.

The proposed CEREC Ortho Software is intended to be used wherever cast impressions are used and in the identical manner in which the traditional physical models are used (i.e., to record topographical characteristics of dentition, gingiva, palate, and/or oral anatomy in conjunction with the treatment planning and production of orthognathic/orthodontic appliances).

5. Indications for Use:

CEREC Ortho Software is intended for use with image data acquired from handheld intra oral 3D cameras and desktop laboratory scanners to create 3D virtual models to be used for data acquisition and modeling analysis for orthodontic patients and conditions. The CEREC Ortho Software 3D model data can be exported to orthodontic design software to aid in the design of orthodontic appliances.

6. Substantial Equivalence:

The CEREC Ortho Software has the same intended use and incorporates the same fundamental technology as the predicate software device. Both the CEREC Ortho Software and the predicate 3Shape Ortho System™ (K152086) are stand-alone software devices which are intended as Orthodontic Treatment Software devices (Product Code PNN, under 21 CFR 872.5470) and, as such are intended to aid in the diagnosis and treatment planning of orthodontic patients and conditions.

Detailed comparison of the intended use and technological characteristics and features of the CEREC Ortho Software and the predicate 3Shape Ortho System™ (K152086) devices is presented in Tables 6.1 and 6.2.

Table 6.1: Indications for Use

Subject Device **CEREC Ortho Software**	**Predicate Device** **3Shape Ortho System™** **(K152086)**
CEREC Ortho Software is intended for use with image data acquired from handheld intra oral 3D cameras and desktop laboratory scanners to create 3D virtual models to be used for data acquisition and modeling analysis for orthodontic patients and conditions. The CEREC Ortho Software 3D model data can be exported to orthodontic design software to aid in the design of orthodontic appliances.	3Shape Ortho System™ is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspections, detailed analysis, treatment simulation and virtual appliance design options (Custom metal bands, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of Ortho System™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received training in the use of the software.

Table 6.2: Technological Characteristics and Features

Proposed Device **CEREC Ortho Software**	**Predicate Device** **3Shape Ortho System™** **(K152086)**
Supported Computer Formats	
- Intended for loading on a personal computer. Minimum requirements: - Functions within Windows 7, 64-bit operating system. - 250 GB hard disk storage. - 8 GB RAM memory. - Intel QuadCore 1.6 GHz processor. - NVidia or AMD graphics card with 1 GB memory.	- Intended for loading on a personal computer. Minimum requirements: - Functions within Windows 7 or 8, 64-bit operating system. - 250 GB hard disk storage. - 8 GB RAM memory. - Intel Core i5 or equivalent processor. - GeForce graphics card with 1 GB memory.
Acquisition Data Formats Support	
Intra-oral scan data	Intra-oral scan data
Desktop scanner STL data	Desktop scanner STL data
N/A	Computed Tomography (CT) DICOM image data
N/A	2D overlay data
Supported anatomic areas	
Maxilla	Maxilla
Mandible	Mandible
Functionality	
Acquisition of oral topography image data	Acquisition of oral topography image data
Creation of virtual 3D virtual dental models	Creation of virtual 3D virtual dental models
Alignment of 3D virtual dental models	Alignment of 3D virtual dental models
Measurement of 3D virtual dental models	Measurement of 3D virtual dentals models
Analysis of 3D virtual dental models	Analysis of 3D virtual dental models
N/A	Orthodontic treatment simulation
N/A	Virtual orthodontic appliance design
Exporting of 3D virtual model and analysis data	Exporting of 3D virtual model, analysis and treatment case data

Table 6.2: Technological Characteristics and Features (continued)

Proposed Device **CEREC Ortho Software**	**Predicate Device** **3Shape Ortho System™** **(K152086)**
Analysis Features	
Occlusal mapping	Occlusal mapping
Tooth and gingiva separation/segmentation	Tooth and gingiva separation/segmentation
Definition of dental arch shape and length	Definition of dental arch shape and length
Tooth width measurements	Tooth width measurements
Bolton's analysis	Bolton's analysis
Nance and Moyer space analyses	Space analyses
Orthodontic Treatment Simulation	
N/A	2D and 3D simulated orthodontic treatment
Virtual Orthodontic Appliance Design	
N/A	Orthodontic appliance search library.
N/A	Virtual placement of orthodontic appliances.
N/A	Design of orthodontic appliances
N/A	Export of orthodontic appliance designs

The CEREC Ortho Software and the predicate 3Shape Ortho System™ (K152086) both facilitate their intended use through the acquisition of image scan data of the oral topography. With the acquired image data, the proposed device and predicate device (K152086) create 3D virtual dental models of the patient's dentition. These virtual dental models are functional equivalents of physical cast models.

The CEREC Ortho Software and the predicate 3Shape Ortho System™ (K152086) automatically provide alignment tools, measurement, and perform analysis of the 3D virtual models. With respect to the proposed CEREC Ortho Software, the 3D virtual model and finalized analysis can be exported to support orthodontic treatment planning. However, in the case of the predicate 3Shape Ortho System™ (K152086), orthodontic treatment planning is also integral to the software device functionality through: simulated orthodontic treatment; virtual design and placement of orthodontic appliances, and export for the finalized orthodontic treatment plan.

7. Non-Clinical Performance Data

In support of the substantial equivalence of the CEREC Ortho Software, performance and software testing were conducted and are included and the results support substantial equivalence:

- Testing to verify the accuracy of the measurement functions of the CEREC Ortho Software as well as the trueness and precision of optical impressions produced using CEREC optical impression systems and the CEREC Omnicam intra-oral scanner (510(k)-exempt under 21 CFR 872.3661).
- Validation of the CEREC Ortho Software in conformity with IEC 62304 (*Medical device software – Software lifecycle processes*).

The CEREC Ortho Software does not include any physical device, accessory, or component with patient contacting intended use. Therefore, no biocompatibility data, sterilization, or shelf life analyses were included in support of substantial equivalence.

8. Clinical Performance Data

No human clinical data was included to support substantial equivalence.

9. Conclusion Regarding Substantial Equivalence

The CEREC Ortho Software has the same intended use as that of the predicate 3Shape Ortho System™ (K152086) software. Both devices are orthodontic software devices regulated under 21 CFR 872.5470 and as such are intended for use to aid in the diagnosis and treatment planning of orthodontic patients and conditions.

The predicate 3Shape Ortho System™ (K152086) is additionally regulated as a Radiological Image Processing System under 21 CFR 892.2050 due to its functionality to utilize CT DICOM images as input. However, the proposed CEREC Ortho Software does not incorporate this functionality and therefore is proposed for an intended use which is a subset of the predicate device (K152086) to which it is compared.

Non-clinical testing and software validation data are included to demonstrate the performance of the CEREC Ortho Software against its design, functional, and safety requirements. The results of the testing support a determination of substantial equivalence.