DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Dentsply Sirona
% Mr. Karl Nittinger
Senior Manager, Corporate Regulatory Affairs
221 West Philadelphia Street, Suite 60W
YORK PA 17401

July 17, 2017

Re: K171115
Trade/Device Name: 3D Endo™ Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: June 26, 2017
Received: June 27, 2017

Dear Mr. 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.

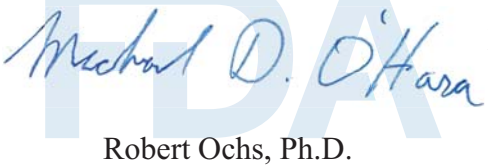
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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,



For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K171115

Device Name
3D Endo™ Software

Indications for Use *(Describe)*
3D Endo™ Software is intended to aid in the visualization, diagnosis and planning of endodontic treatment and re-treatment cases utilizing DICOM images.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5. 510(k) SUMMARY
for
3D Endo™ Software

5.1 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: April 13, 2017

5.2 Device Name: 3D Endo™ Software

Proprietary Name: 3D Endo™ Software
Classification Name: Picture archiving and communications system
CFR Number: 892.2050
Device Class: II
Product Code: LLZ

5.3 Predicate Device:

Table 5.0 Predicate Device Information

Predicate Device Name	510(k) number	Company Name
SimPlant 2011	K110300	Dentsply Implants

5.4 Description of Device:

The proposed 3D Endo™ Software is image processing software for simulating 3D images using Digital Imaging and Communication in Medicine (DICOM) images of the respective tooth and the surrounding tissue. The DICOM images used by the proposed 3D Endo™ Software are imported from those generated by Cone Beam Computed Tomography (CBCT) scanners. The proposed 3D Endo™ Software has no direct control or interface with the CBCT Scanner.

This imaging is used to provide a means for pre-operative planning for endodontic root canal procedures. The proposed 3D Endo™ Software is stand-alone software, with no physical component. It is downloaded and locally installed on the end user's computer system, and updated automatically as required through an active internet connection.

The proposed 3D Endo™ Software allows a user to create a 3D image from DICOM images using a 5 step process. The user can diagnose their case, visually isolate the tooth of interest and surrounding soft and osseous tissue, investigate the canal system, understand the 3D canal anatomy, and create a treatment plan by following the steps laid out in the software's wizard.

The proposed 3D Endo™ Software functions by processing 2D images received in DICOM format from a CBCT scanning device, and processing multiple images into a virtual 3D image. The user can measure, assess, and visualize the anatomy of the root canal structure, both with and without simulated instruments, allowing the practitioner to plan the endodontic procedure. While the proposed 3D Endo™ Software is classified as a picture archiving and communication system, the system does not communicate patient data such as DICOM images through the internet. The proposed 3D Endo™ Software functions by accessing DICOM images either stored locally on the system hard drive by the user, or by accessing DICOM images stored on media (e.g. CD/DVD, USB drive) attached to the local system on which proposed 3D Endo™ Software is installed. By default, the proposed 3D Endo™ Software does not export and store any patient data to the local hard drive. Upon explicit action by the user, an encrypted project file may be saved or a PDF report can be generated. The proposed 3D Endo™ Software provides an extra function to anonymize the dataset.

5.5 Indications for Use:

3D Endo™ Software is intended to aid in the visualization, diagnosis and planning of endodontic treatment and re-treatment cases utilizing DICOM images.

5.6 Substantial Equivalence

Table 5.1 Comparison between 3D Endo™ Software and SimPlant 2011(K110300)				
No	**Feature**	**Proposed Device** **3D Endo™ Software**	**Predicate Device** **SimPlant 2011(K110300)**	**Similarities/Differences**
1	Indications for Use	3D Endo™ Software is intended to aid in the visualization, diagnosis and planning of endodontic treatment and re-treatment cases utilizing DICOM images.	SimPlant 2011 is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance scanner. It is also intended as pre-planning software for dental implant placement and surgical treatment.	The proposed 3D Endo™ Software utilizes DICOM images from CBCT only. The proposed 3D Endo™ Software is intended specifically for endodontic treatment and re-treatment cases (root canal)..
2	Intended use	Software for use in endodontic (root canal) pre-operative planning: • The proposed 3D Endo™ Software Provides a means for transferring DICOM patient images from a CBCT scanner to an output file • The proposed 3D Endo™ Software is used to provide a means for advanced pre-operative planning of endodontic treatment, including root canal visualization and endodontic files selection support The proposed 3D Endo™ Software is used to provide a means for DICOM Image Visualization	Software for use in implants pre-operative planning: • SimPlant 2011 Provides a means for transferring patient images from a medical scanner to an output file • SimPlant 2011 is used to provide a means for advanced pre-operative planning of dental implant placements and orthognathic treatment • SimPlant 2011 is used to provide a means for image segmentation Surgical templates may be designed and fabricated based on the output of the pre-operative planning	The proposed 3D Endo™ Software utilizes DICOM images from CBCT only. The proposed 3D Endo™ Software is intended specifically for endodontic treatment and re-treatment cases (root canal).
3	Image Modality	CBCT	MRI, CT, CBCT	The proposed 3D Endo™ Software utilizes only CBCT scanning data
4	Input File Type	DICOM	DICOM	No differences
5	Optional output files	PDF report Proprietary project file	Proprietary project file	No differences

Table 5.1 Comparison between 3D Endo™ Software and SimPlant 2011(K110300)				
No	**Feature**	**Proposed Device 3D Endo™ Software**	**Predicate Device SimPlant 2011(K110300)**	**Similarities/Differences**
6	Used for Pre-operative Planning	Yes	Yes	No differences
7	Operating System	Windows	Windows	No differences
8	Principles of operation	Desktop software application	Desktop software application	No differences
9	Functions	Volume Rendering with tooth/bone emphasizing transfer functions	Volume Rendering with tooth/bone emphasizing transfer functions	No differences
		Volume Rendering	Segmentation Wizard	The proposed 3D Endo™ Software utilizes Volume Rendering, a less complex methodology suited to the endodontic requirements of the software
		Reslice the volume data along a predefined path for view of the tooth axis or a single root canal midline (Intra-Root view)*	Reorient axial images to occlusal plane	No differences
		Open project	Open project	No differences
		Save project	Save project	No differences
		3D viewing	3D viewing	No differences
		2D gray value images	2D gray value images	No differences
		Tooth geometry and anatomy presentation	Geometry presentation	No differences
		Measurements (distance, angle, diameter) **	Measurements	No differences
		Review the endodontic files	Review implants	No differences
		Edit the endodontic files	Edit implants	No differences
		Change the endodontic files	Change implant	No differences
		Not Applicable	Collision detection	Dissimilar
		Simulated panoramic / X-ray view	Simulated panoramic / X-ray view	No differences

Table 5.1 Comparison between 3D Endo™ Software and SimPlant 2011(K110300)				
No	**Feature**	**Proposed Device** **3D Endo™ Software**	**Predicate Device** **SimPlant 2011(K110300)**	**Similarities/Differences**
		Semi-Automatic canal midline finding	Not applicable	Specific to proposed 3D Endo™ Software
		Endodontic files deformation along the indicated canal midline	Not applicable	Specific to proposed 3D Endo™ Software
		Access cavity curve simulation	Not applicable	Specific to proposed 3D Endo™ Software
		Endodontic files visualization	Not applicable	Specific to proposed 3D Endo™ Software

* Once the tooth axis is manually defined (cropping) or the canal midline is manually indicated, the resliced views are automatically generated.

** These are free measurements able to define a number of functions, including working length, tooth size, and other procedurally important definitions.

5.7 Analysis of differences between Proposed and Predicate Devices:

The proposed 3D Endo™ Software is similar to predicate SimPlant 2011 (K110300) in basic technology; since both devices processes the DICOM (Digital Imaging and Communication in Medicine) images received from CBCT (Cone Beam Computed Tomography) scanners to create 3D images of tooth and surrounding tissue anatomy. Both devices utilizes same image format (DICOM image files) from same image source (CBCT scanner). The proposed 3D Endo™ Software and SimPlant 2011 (K110300) are intended to aid in planning for dental Endodontic treatment procedure using 3D images. Both devices are desktop software applications running on windows operating system with similar software features such as taking measurements, simulated panoramic/X-ray view, tooth geometry presentation, 2D gray value images, open and save projects.

The dissimilar aspects of the proposed 3D Endo™ Software as compared to the SimPlant 2011 (K110300) software are related to the variant uses of the two software packages. The predicate SimPlant 2011 (K110300) software is intended to be used as a pre-planning software for dental implant placement and surgical treatment, and the proposed 3D Endo™ Software is intended for use in the visualization, diagnosis and planning of endodontic treatment and re-treatment cases.

The proposed 3D Endo™ Software is used to provide a means for advanced root canal visualization and endodontic files selection support hence functionalities related to the visualization of soft and osseous tissue, virtual occludation, and surgical guidance are not required to fulfill the intended usage of the proposed 3D Endo™ Software as compared to SimPlant 2011 (K110300) functionalities.

Because 3D Endo™ Software is used to provide a means for advanced root canal visualization and endodontic files selection, the proposed 3D Endo™ Software utilizes Volume Rendering in its functionality as opposed to the more complex segmentation used by SimPlant 2011 (K110300). These dissimilarities are therefore only related to specific variations of the uses of the imaging software, and do not relate to the fundamental technology or similarities in the intended uses of the two devices. Dentsply believes that segmentation differences do not create any new questions about safety, effectiveness and substantial equivalence as evidence by software verification and validation provided in this submission.

5.8 Non-Clinical Performance Data:
The proposed 3D Endo™ Software is a software device with no physical component. It does not incorporate, nor does it control a patient contacting device or material. Therefore, no biocompatibility, sterilization, shelf life, animal, or clinical testing was included to support substantial equivalence. The performance of proposed 3D Endo™ Software satisfactorily met the requirements of the non-clinical bench testing conducted to support substantial equivalence. Software verification and validation was conducted in accordance with the software life cycle processes, as defined in IEC 62304 to ensure the functionality and compatibility of all system components and to support the substantial equivalence of the proposed 3D Endo™ Software. Test data has been provided including: software unit testing, software integration/functional testing, and regression testing in software section. Software testing demonstrated compliance with the requirements of the IEC 62304 standard. In addition to the software validation and verification testing, the following testing was performed on proposed 3D Endo™ Software and was included to support substantial equivalence.

Table 5.2 Performance Test for 3D Endo™ Software			
No	**Test**	**Objective**	**Results**
1	Usability Test	Usability testing was conducted as per IEC 62366-1:2015: Medical devices-Part 1: Application of usability engineering to medical devices and as per FDA guidance Applying Human Factors and Usability Engineering to Medical Devices to determine ease of use, and potential human usage errors utilizing the standard System Usability Scale (SUS), as well as providing evidence that the software meets user needs and intended use.	There were no results demonstrating the presence of new or unexpected use errors which present a serious residual use-related risk to the user or patient.

5.9 Clinical Performance Data

No human clinical data is included in this premarket notification to support substantial equivalence.

5.10 Conclusion Regarding Substantial Equivalence:

The proposed 3D Endo™ Software is DICOM image visualization software which is intended to aid in the visualization, diagnosis and planning of endodontic treatment and re-treatment cases using DICOM images received from a CBCT Scanner.

The proposed 3D Endo™ Software has the same intended use, incorporates the same fundamental technology, and has similar indications for use as the predicate SimPlant 2011 software cleared under premarket notification K110300. Test data to verify the performance of the proposed 3D Endo™ Software has been provided including: software unit testing, software integration/functional testing, and regression testing. The results of this testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence.