DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 28, 2016

Dentsply Sirona
% Ms. Helen Lewis
Director, Corporate Regulatory Affairs
221 West Philadelphia Street
Suite 60
YORK PA 17404

Re: K161118
Trade/Device Name: SIMPLANT Online Case Review and SIMPLANT Editor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 7, 2016
Received: July 8, 2016

Dear Ms. 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 yours,

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)*
K161118

Device Name
SIMPLANT Online Case Review and SIMPLANT Editor

Indications for Use *(Describe)*
SIMPLANT Online Case Review and SIMPLANT Editor are indicated for use as medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. These are intended for use as pre-operative software programs for generating and reviewing plans for dental implant placement and surgical treatment.

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

SECTION 5. 510(k) SUMMARY
for
SIMPLANT Online Case Review and SIMPLANT Editor

1. Submitter Information**:**

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

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

Date Prepared: April 15, 2016

2. Device Name:

Proprietary Name: SIMPLANT Online Case Review and SIMPLANT Editor
Classification Name: Picture Archiving and Communication System
CFR Number: 21 CFR §892.2050
Device Class: Class II
Product Code: LLZ

3. Predicate Device:

The medical device SimPlant 2011 was selected as the predicate device for this submission for the proposed devices SIMPLANT Online Case Review and SIMPLANT Editor. Simplant 2011 is designed, developed and manufactured by DENTSPLY Implants NV (formerly Materialise Dental NV) and cleared for the US market in K110300.

4. Description of Device:

The proposed devices, SIMPLANT Online Case Review and SIMPLANT Editor, are software intended for pre-operative planning to generate and review plans for dental implant placement and surgical treatment, without patient contact.

SIMPLANT Online Case Review is a web application used for review and approval of dental implant plans provided by DENTSPLY Implants. SIMPLANT Online Case Review can also be used in combination with the desktop software application SIMPLANT Editor when an implant plan, provided by DENTSPLY Implants, is edited by the dental professional.

The software SIMPLANT Online Case Review and SIMPLANT Editor are used by dental professionals with clinical experience in implant surgery as well as training in medical image review.

Implant plans, in the format of SIMPLANT project files are created by DENTSPLY Implants and made available to the dental professional. The SIMPLANT project is created by DENTSPLY Implants using dental professional supplied patient image data, patient information and implants data developed by DENTSPLY Implants which are merged together. The SIMPLANT project is the basis for implant surgery planning by dental professionals.

The dental plan, which is the result of the dental implant planning process, can be used for manufacturing a surgical guide or for evaluation of treatment options by the dental professional during the implant surgery procedure.

5. Indications for Use:

SIMPLANT Online Case Review and SIMPLANT Editor are indicated for use as medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. These are intended for use as pre-operative software programs for generating and reviewing plans for dental implant placement and surgical treatment.

6. Substantial Equivalence:

Technological characteristics

The proposed devices, SIMPLANT Online Case Review and SIMPLANT Editor, are stand-alone medical device software used without patient contact.

Table 5-1 Substantial equivalence comparison table

Element	**Proposed Devices**		**Predicate Device**	**Diffe-rence**
	SIMPLANT Online Case Review	**SIMPLANT Editor**	**Simplant 2011 (K11300)**	
Indications for Use	SIMPLANT Online Case Review and SIMPLANT Editor are indicated for use as medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. These are intended for use as pre-operative software programs for generating and reviewing plans for dental implant placement and surgical treatment.		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.	Yes
Intended Purpose	Review and approve implant plan	Edit implant plan for approval in Online Case Review.	Create, edit and approve implant plan.	Yes
Function			Volume Rendering	Yes
			Segmentation Wizard	Yes
			Reorient axial images to occlusal plane	Yes
			Advanced virtual teeth	Yes
			Advanced grafts and Volumes	Yes
			Dual scan registration	Yes

Element	Proposed Devices		Predicate Device	Diffe-rence
	SIMPLANT Online Case Review	**SIMPLANT Editor**	**Simplant 2011 (K11300)**	
			Optical scan registration	Yes
			Occlusion tool	Yes
			Virtual occludator*	Yes
			Advanced soft tissue simulation	Yes
			Surgical guide wizard	Yes
		Open project	Open project	No
		Save project	Save project	No
	Load project		Load project	No
	3D viewing	3D viewing	3D viewing	No
	2D gray value images	2D gray value images	2D gray value images	No
	Navigation	Navigation	Navigation	No
			Review and accept nerve	Yes
	Distance	Distance	Distance	No
	Geometry presentation	Geometry presentation	Geometry presentation	No
	Measurements	Measurements	Measurements	No
	Review implants	Review implants	Review implants	No
		Edit implants	Edit implants	No
		Change implant	Change implant	No
	Collision detection	Collision detection	Collision detection	No
	Approve plan		Approve plan	No
Media for Delivery	Web application	Software-File for download	Software-Magnetic media	Yes
Principles of operation	Web application	Desktop software application	Desktop software application	Yes
Program language	C#	C++	C++	Yes
Operating System	Windows	Windows	Windows	No

*Occludator means a function to visualize how the upper and lower jaw will come together when the mouth is closed.

Analysis of differences

The proposed devices compared to the predicate have similar indications for use and partly the same basic functionalities. The first 11 functions listed in Table 5-1 for the predicate device are used during creation of an implant plan, which will not be performed with any of the proposed devices. The differences here are due to the proposed devices', SIMPLANT Online Case Review and SIMPLANT Editor's dependency to a pre-created implant plan made by DENTPLY Implants.

The 'Review and accept nerve' function is no longer included in the software applications as a separate function. For the proposed devices, SIMPLANT Online Case Review and SIMPLANT Editor, the nerve is accepted implicitly when the complete dental implant plan is approved by the dental professional.

The differences in principles of operation and media for delivery are due to the simplification of the review process for the dental professional allowing them to view implant plans in the web application SIMPLANT Online Case Review. This does not require transfer of all the data in the implant plan to a local computer nor is a local installation of a software application required.

The differences in programming languages are also due to principles of operation and the fact that SIMPLANT Online Case Review is a web application. For this reason, C# is selected for its suitability to support development of web applications.

7. Software testing

Software verification and validation was conducted to ensure the functionality and compatibility of all system components and to support the safety and effectiveness of the proposed devices.

The software testing has been compared to the predicate device, Simplant 2011 (K110300), image accuracy testing and tests applied in accordance with the software life cycle processes, as defined in IEC 62304.

The verification and validation testing consists of the following activities:

- Unit test
- Peer Code Review
- Integration test
- Internal release test
- Smoke test
- Formal system test
- Acceptance test
- Beta test

Verification and validation testing confirms that all user needs and performance requirements according to the design input are fulfilled. The comparison tests confirm the functionality, safety and efficacy of the proposed devices.

8. Conclusion Regarding Substantial Equivalence

The SIMPLANT Online Case Review and SIMPLANT Editor are dental software which are intended for use as a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. The SIMPLANT Online Case Review and SIMPLANT Editor are intended for use as pre-operative software programs for generating and reviewing plans for dental implant placement and surgical treatment.

The SIMPLANT Online Case Review and SIMPLANT Editor have similar indications for use and incorporate the same fundamental functions as the predicate device SimPlant 2011 cleared under premarket notification K110300. Test data to verify the performance of the SIMPLANT Online Case Review and SIMPLANT Editor have been provided, where the results of this testing, combined with the comparison to the predicate device, support substantial equivalence and do not raise any new issues of safety or effectiveness.