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

April 4, 2018

Re: K172239
Trade/Device Name: SIMPLANT 18
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 20, 2018
Received: February 26, 2018

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.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172239

Device Name
SIMPLANT 18

Indications for Use *(Describe)*

SIMPLANT 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. It is also intended as pre-planning software 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 60W
York, PA 17401

510(k) SUMMARY
For
S1MPLANT 18

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: February 22, 2018

2. Device Name:

- Proprietary Name: Simplant 18
- Classification Name: Picture archiving and communications system
- CFR Number: 892.2050
- Device Class: II
- Product Code: LLZ

3. Predicate Device:

Predicate Device Name	510(k)	Company Name
SimPlant 2011	K110300	Materialise Dental NV

4. Description of Device:

The proposed device SIMPLANT 18 is stand-alone software intended for pre-operative planning of dental implant placement and surgical treatment options, without patient contact.

A SIMPLANT project file is created from patient image data, patient information, and implants data which are aggregated together. The SIMPLANT project file is the basis for continued implant surgical planning by dental professionals.

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

The purpose of this premarket notification is to gain clearance for new features implemented in the latest software version, clarification of the indications for use, as well as to document iterative changes to the software that have been implemented since the original clearance under K0110300.

5. Indications for Use:

SIMPLANT 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. It is also intended as pre-planning software for dental implant placement and surgical treatment.

6. Substantial Equivalence:

Technological Characteristics:

The proposed SIMPLANT 18 is stand-alone medical device software, used without patient contact.

Table 5-1 Substantial Equivalence Comparison Table

Element	**Proposed device** SIMPLANT 18	**Predicate device** SimPlant 2011 K110300	**Difference**
Manufacturer	DENTSPLY Implants NV (formerly Materialise Dental NV)	Materialise Dental NV	No
Indications for use	SIMPLANT 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. It is also intended as pre-planning software 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
User	Medically trained people.	Medically trained people.	No
Functions	**File open/save tools**		
	(CB)CT images import	(CB)CT images import	No
	Open project	Open project	No
	Save project	Save project	No
	Visualization tools		
	2D gray value images	2D gray value images	No
	3D viewing	3D viewing	No
	Navigation (Zoom/Pan/Rotate)	Navigation (Zoom/Pan/Rotate)	No

Element	Proposed device SIMPLANT 18	Predicate device SimPlant 2011 K110300	Difference
	Volume rendering	Volume rendering	No
	Segmentation tools		
	Segmentation wizard	Segmentation wizard	No
	Measurement tools		
	Distance	Distance	No
	Angle	Angle	No
	Density	Density	No
	Preparation tools		
	Dual scan registration - Soft tissue creation possibility	Dual scan registration - No soft tissue creation possibility	Yes
	Optical scan registration - Intraoral scan - Plaster cast scan and additional 3D model scans	Optical scan registration - Intraoral scan - Plaster cast scan	Yes
	Panoramic curve	Panoramic curve	No
	Nerve	Nerve	No
	Improved Virtual teeth	Virtual teeth	Yes
	Grafts and volumes	Grafts and volumes	No
	Reorient axial images to occlusal plane	Reorient axial images to occlusal plane	No
	Planning tools		
	Implant Library - Immediate smile featuring Atlantis abutment	Implant Library	Yes
	Place implant	Place implant	No
	Draw implant	Draw implant	No
	Edit implant - Multiple implant Movement	Edit implant	Yes
	Collision detection	Collision detection	No
	Request SIMPLANT guide wizard	Request SIMPLANT guide wizard	Yes

Element	Proposed device SIMPLANT 18	Predicate device SimPlant 2011 K110300	Difference
	- with automatic transfer to mySIMPLANT.com	- with automatic transfer to Online Shop	
	-	Occlusion tool Virtual occludator Soft tissue simulation	Yes
Media for delivery	Software - file for download.	Software - magnetic media (DVD).	Yes
Principles of operation	Desktop application.	Desktop application.	No
Program language	C++	C++	No
Operating system	Windows	Windows	No

Analysis of differences:

The indications for use statement has been clarified to remove the example related to image import from a magnetic resonance scanner as it is not possible to import data from magnetic resonance scanning equipment into the subject SIMPLANT software.

Functionality changes are implemented to improve usability:

- Scan registration is expanded to allow for soft tissue creation and for import of 3D model scans to help the user when determining the ideal implant position. The improved Virtual teeth function offers more options and flexibility to shape and position the virtual teeth. The additional "multiple implant movement" function makes it easier for a user to simultaneously alter the positions of more than one implant relative to the bone, thereby maintaining their initial positions relative to one another.
- In the predicate device, the complete Implant library had to be downloaded for each library update. In the proposed device, a partial upload is possible, and as such, reduces the download time for the user.
- The new feature "Immediate Smile featuring Atlantis abutments" makes it easier for the user to see which implants are compatible with customized ATLANTIS Abutments. Also, the design of this abutment can be imported and made visible in the planning file of the proposed SIMPLANT 18.

The "Occlusion tool", "Virtual occludator" and "Soft tissue simulation" functions have been removed from the software's functionality.

The website for ordering patient specific surgical guides has changed. Consequently, the proposed SIMPLANT 18 directs the user automatically to the new mySIMPLANT web page instead of to the former Online Shop for ordering the guide.

The media for delivery of the proposed device has been changed. The original software was delivered on DVD, whereas the proposed device is delivered via file download for installation.

Summary of Software testing:

Software verification and validation was conducted to ensure the functionality and have been included to support the substantial equivalence of the subject SIMPLANT 18 software.

In principle, the software testing has consisted of testing of the software functionality containing the changes introduced since the approved predicate device SimPlant 2011 (K110300). . Software testing has been conducted in accordance with the software life cycle processes, as defined in IEC 62304.

The verification and validation testing has consisted of the following activities:

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

The results of verification and validation confirm that all user needs and performance requirements according to the design inputs are fulfilled.

7. Conclusion Regarding Substantial Equivalence:

The proposed SIMPLANT 18 is software 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. It is also intended as pre-planning software for dental implant placement and surgical treatment.

The proposed SIMPLANT 18 software, which is the subject of this premarket notification, has the same intended use and similar indications for use, incorporates the same technological characteristics and principles of operation as the predicate SimPlant 2011 (K110300) device. SIMPLANT 18 is tested and validated in the same way as the predicate SimPlant 2011 (K110300) device. Test data to verify the performance of the proposed SIMPLANT 18 have been included and the results of this testing confirmed the functionality and support the substantial equivalence of the proposed device SIMPLANT 18.