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

Sirona Dental Systems GmbH
% Mr. Kofi Aninakwa
Legal Services Engineer
Sirona Dental Systems, Inc.
30-30 47th Avenue, Suite 500
LONG ISLAND NY 11101

May 8, 2015

Re: K150217
Trade/Device Name: ORTHOPHOS SL
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: April 13, 2015
Received: April 17, 2015

Dear Mr. Aninakwa:

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K150217

Device Name
ORTHOPHOS SL

Indications for Use *(Describe)*
The X-ray system creates data for digital exposures in the maxillofacial area and in subareas for dentistry, including pediatric dentistry, for hard-tissue diagnostics within ENT medicine, and for carpus exposures.

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."

510(k) Summary

For

Sirona Dental Systems

ORTHOPHOS SL

1 SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany

Contact Person: Kofi Aninakwa
Telephone: 718-482-2248
Date Prepared: January 19 2015

2 DEVICE NAME

Proprietary Name: ORTHOPHOS SL
Common/Usual Name: X-Ray, Tomography, Computed, Dental
Classification Name: Computed Tomography X-ray system
Classification Number: 21 CFR 892.1750 - Computed Tomography X-ray system
Product Code: OAS – X-ray, Tomography, Computed, Dental

3 PREDICATE DEVICES

- Sirona ORTHOPHOS XG 3D / Ceph (K103711)
  Classification Number: 21 CFR 892.1750 - Computed Tomography X-ray system
  Product Code : OAS
- Sirona GALILEOS Comfort Plus (GALILEOS Family - K123070)
  Classification Number: 21 CFR 892.1750 - Computed Tomography X-ray system
  Product Code : OAS

  The primary predicate device is ORTHOPHOS XG 3D / Ceph. This is because ORTHOPHOS SL is a further development of ORTHOPHOS XG3D and as such both have very similar functionality. The PC software of ORTHOPHOS SL has similar functions and operations as that of GALILEOS Comfort Plus.

4 INTENDED USE

The X-ray system creates data for digital exposures in the maxillofacial area and in subareas for dentistry, including pediatric dentistry, for hard-tissue diagnostics within ENT medicine, and for carpus exposures.

5 DEVICE DESCRIPTION AND FUNCTION

The device comprises image receptors for cephalometric exposures, 2D panoramic radiographs and 3D volume exposures. The combination of sensors in the device varies depending on the installed options and the regions of interest can be altered. The technology behind this is collimation and different start- and end angles of exposure. These allow for a reduced dosage depending on the program selected. This function is available with some volume, cephalometric and panoramic programs.

Class I laser beam light localizers aid in the positioning of a patient's head which may be fixed through the use of bite blocks and adjustable forehead and temple supports.

From the obtained exposures, reconstructed images can be viewed. The reconstructed 3D volumes, simulated projection exposures and panoramic/cephalometric data can be conveyed to SIDEXIS (an FDA approved Sirona software for acquisition, administration, analysis, diagnosis, presentation and transfer of image data for medical/dental use) and stored in the SIDEXIS database.

An operator control panel allows for height adjustment, selection of mode and program, and indication of machine states. A separate handheld push-button serves for exposure release and an optional remote control is available.

5.1 Scientific concept

The underlying scientific concept of the 3D volumes, is the cone-beam x-ray technology. New direct conversion sensors are used to reduce the loss of information along with an autofocus feature that eliminates the need to preselect exact jaw shapes for panoramic exposures. The panoramic and cephalometric exposures are obtained by the standard technology that have been used in dental medicine for a very long time.

5.2 Physical and Performance Characteristics

5.2.1 Design

The ORTHOPHOS SL comprises a support stand to which a height adjustable sled is attached. The sled carries the patient fixation, the operator control panel (easy pad) and

the motor driven rotatable ring. The X-ray source and image receptor are fixed to the ring. During a scan the device generates an x-ray beam that rotates around the patient´s head at varying angles.

The exposure area is defined by the geometry of the ORTHOPHOS SL.
A control panel allows the user to select the exposure modes and the exposure factors, view the machine status information, control the height adjustment and turn on the laser indicator.

The PC software reconstructs the three-dimensional image as well as processes panoramic / cephalometric images. The constructed 3D volume and simulated projection exposures as well as panoramic/ cephalometric data are conveyed to SIDEXIS and stored in the SIDEXIS database.

New features include a Direct Conversion Sensor and an autofocus feature that eliminates the need to preselect exact jaw shapes for panoramic exposures. These have been tested in a system test. An Oral Surgeon report provided also covers these features.

5.2.2 Materials Used

Materials that come into patient contact intentionally are biocompatible and evaluated according to ISO 10993-1: 2003, "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process".

5.2.3 Physical Properties

Not applicable.

5.3 Software Level of Concern

The ORTHOPHOS SL software was determined to be of a MODERATE level of concern.
The software of the OTHOPHOS SL has been modified to support the new hardware. Software adaptations have been made to include the new autofocus for panoramic X-ray images, the Acquisition server and the new choice of x-ray programs.

6 SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The ORTHOPHOS SL is a further development of the ORTHOPHOS XG3D (USA 510(k)-K103711).

The ORTHOPHOS SL has a different source to skin distance than the ORTHOPHOS XG3D and the amount of images during an exposure has been increased.

The ORTHOPHOS SL is capable of a range of x-ray parameters. The tube voltage can vary between 60kV and 90kV. The tube current can vary between 6mA and 12mA with an addition current of 16mA at 66kV. The maximum is 90kV and 12 mA.

A new sensor type is integrated in the ORTHOPHOS SL. It is a direct conversion sensor.

The PC software performs identical functions and algorithms as the GALILEOS. The software has been adapted to the higher number of images.

The ORTHOPHOS SL offers a calculated panoramic view in combination with slices orthogonal to the panoramic curve ('transversal slices') as the predicate GALILEOS for volumes. The GALILEOS family offers nearly the same functionality in viewing slices, projections and volume views for volume exposures.
ORTHOPHOS SL looks similar to the predicate ORTHOPHOS XG 3D, but the color of the operator panel differs. The panel is new, but the main difference is a color change. The offered functions for the operator are nearly the same.

In comparison to ORTHOPHOS XG 3D, ORTHOPHOS SL has an additional class I laser light beam localizer that helps the user identify volume size. The principles of the patient fixation for both devices are the same.

ORTHOPHOS SL has more volume sizes, volume positions and collimations than the predicate devices. This results in more possibilities to get an exposure of relevant dentomaxillofacial areas.

The ORTHOPHOS SL has a higher dose area product than ORTHOPHOS XG 3D due to demand from medical professionals to use with patients with dense bone, patients who are overweight and also due to the larger size of the detector.

7 NONCLINICAL TESTING

The ORTHOPHOS SL system functions have been tested in a system test (covers the requirements from the function specification, the risk/hazard analysis and the functionality of the equipment from the user's perspective).

The exposure programs have been tested utilizing test phantoms. The tests evaluate the equality of exposures of proposed ORTHOPHOS SL and predicate device ORTHOPHOS XG 3D.

Additional tests have been performed taking into account FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, Document issued on: August 6, 1999" adapted for image intensifier products. In particular, DQE and MTF data in 3D mode for the Hamamatsu detector mode have been provided to demonstrate substantial equivalence.

Finally, The ORTHOPHOS SL Device complies with the applicable requirements of the following international and national standards:

- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: electromagnetic compatibility - Requirements and Tests
- EN 60601-1:2006 + Corr.:2010 + A1:2013 (IEC 60601-1:2005 + Cor.:2006 + Cor.:2007 + A1:2012) - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Edition 3.1)
- IEC/EN 60601-1-3:2008 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability, (with third edition of 60601-1)
- IEC 60601-2-63:2012 Medical electrical equipment - Part 2-63: Particular Requirements For The Basic Safety And Essential Performance Of Dental Extra-Oral X-Ray Equipment
- IEC 62304: 2006 Medical Devices - Software life cycle processes
- IEC 62366:2014 Medical devices - Application of usability engineering to medical devices
- IEC 60336:2005 Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots.
- IEC 60825-1:2007 Safety of laser products - Part 1: Equipment classification, requirements and requirements
- IEC 62471:2006, Photobiological safety of lamps and lamp systems
- ISO 14971:2007 Medical devices – Application of risk management to medical devices
- ISO 10993-1:2009 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management system

8 CLINICAL TESTING

Sample clinical images have been provided. These were accompanied with Oral Surgeon reports asserting the general diagnostic quality of the images.

9 CONCLUSION

Based on the comparison of intended use, construction, and technical features, Sirona Dental Systems believes that the ORTHOPHOS SL is substantially equivalent to the Sirona ORTHOPHOS XG 3D/CEPH **(**K103711**)** and the Sirona GALILEOS (K123070).