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

June 22, 2020

Re: K201140
Trade/Device Name: Axeos
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: April 24, 2020
Received: April 29, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K201140

Device Name
Axeos

Indications for Use *(Describe)*

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

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510(k) SUMMARY

K201140

1. Submitter Information:

Dentsply Sirona
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York, PA 17404

Contact Person: Karl Nittinger
Telephone Number: 717-849-4424
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Email Address: karl.nittinger@dentsplysirona.com

Date Prepared: May 21, 2020

2. Device Name:

Proprietary Name: Axeos
Classification Name: Computed Tomography X-ray system
CFR Number: 21 CFR 892.1750
Device Class: Class II
Product Code: OAS

3. Predicate Device:

The predicate and reference devices identified relating to the substantial equivalence of the Axeos are:

Primary Predicate Device Name	510(k)	Company Name
Orthophos SL	K150217	Sirona Dental Systems GmbH (Owner Operator: Dentsply Sirona, Inc.)

Classification Name: Computed Tomography X-ray system
CFR Number: 21 CFR 892.1750
Device Class: Class II
Product Code: OAS

Reference Device	510(k)	Company Name
SIDEXIS 4	K132773	Sirona Dental Systems GmbH (Owner Operator: Dentsply Sirona, Inc.)

Classification Name: Picture archiving and communication system

CFR Number: 21 CFR 892.2050
Device Class: Class II
Product Code: LLZ

4. Description of Device

The proposed Axeos is a dental cone-beam CT system (CBCT), which comprises sensor units for 2D cephalometric exposures, 2D panoramic radiograph and 3D volume exposure. The combination of sensors varies depending on the installed device configuration. In the proposed device, the 2D sensor, as well as the 2D cephalometric sensor, are identical to the corresponding sensors utilized in the predicate device (K150217). However, with respect to the 3D CBCT exposures, the proposed Axeos device utilizes a new version of the flat panel sensor with a larger field of view compared to the flat panel version utilized within the predicate Orthophos SL (K150217).

The proposed Axeos device uses an x-ray beam that rotates around the patient's head. Detectors acquire two-dimensional x-ray images at varying radiographic angles. An enhanced software algorithm generates the 2D panoramic and 2D cephalometric images and the reconstruction algorithm reconstructs the 3D volumetric image from the raw image data.

The exposed area can be adapted to a specific region of interest to keep the radiation dose as low as possible for the patient. This is achieved by collimating the x-ray beam and the adjustment of starting and ending points of the sensor/x-ray source movement. Furthermore, the radiation dose can be adapted by various parameters such as program types and exposure technique factors. These functions are available for CBCT, cephalometric and panoramic exposures.

A Class I laser beam is utilized to define reference lines for the correct patient position. The patient is stabilized through different bite blocks and the motor-driven forehead and temple supports.

The obtained digital image data are processed to provide a reconstructed image to the operator/user. The reconstructed images are transferred to the currently marketed SIDEXIS 4 image processing software (K132773) and stored in the SIDEXIS 4 software database. The proposed Axeos device uses the same Sidexis 4 image processing software (K132773) as does the predicate device (K150217) and there are no changes to the SIDEXIS 4 software (K132773) introduced in this premarket notification.

The proposed Axeos device includes metal artifact reduction software feature which automatically reduces image artifacts caused by radiopaque objects. This identical software feature is also included in the predicate Orthophos SL (K150217) device and remains unchanged in the proposed device.

A user control panel allows user actions as: height adjustment, selection of programs, and exposure parameters and delivers information about the unit status.

For 3D imaging, the proposed Axeos allows the user to select volume sizes within which multiple fields of view, anatomic positions, and collimation may be selected. This is intended to allow the clinician to select the field of view based on the diagnostic need and to minimize the dose exposed to the patient. The table below summarizes the selectable 3D imaging choices available to the clinician.

			Collimation: Upper jaw		Collimation: Lower jaw	
	Diameter in cm	Height in cm	Diameter in cm	Height in cm	Diameter in cm	Height in cm
Vol1	8	8	8	5.5	8	5.5
Vol 2	-	-	5	5.5	5	5.5
Vol 3	11	10	11	7.5	11	8.0
Vol 4	17	13	17	7.5	17	10

The main components of the proposed Axeos device are:

- X-ray source
- X-ray detector (flat panel and/or PAN sensor)
- Operator panel
- Laser locator
- Cephalometric arm with detector (Ceph sensor)
- Remote control (only by wire).
- Test phantoms: Exposure phantom, Constancy test phantom, Contrast element, and Ceph test phantom.

5. Indications for Use

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

6. Substantial Equivalence

The subject Axeos has the same intended use as the predicate device Orthophos SL (K150217). Both the Axeos and the primary predicate device are intended as Computed Tomography X-ray systems under 21 CFR 892.1750.

The proposed Axeos device and predicate Orthophos SL (K150217) incorporate the same functional imaging capabilities (2D panoramic, 2D cephalometric, and 3D volumetric imaging). The principles of operation and patient fixation features of both the proposed and predicate (K150217) devices are identical as is the overall workflow principals.

The primary differences between the proposed Axeos and predicate (K150217) devices is the difference in utilized 3D flat panel sensor. The proposed device utilizes a new version of the flat panel sensor with a larger field of view compared to the flat panel version utilized within the predicate Orthophos SL (K150217). In addition, the proposed Axeos does not include image visualization with lingual-buccal exploration, while the predicate device (K150217) includes this functionality.

Indications for Use

Predicate Device Orthophos SL (K150217)	Proposed Device Axeos
The X-ray system creates data for digital exposures in the maxillofacial area and in subareas for dentistry and pediatric dentistry, for hard-tissue diagnostics within ENT medicine, and carpus exposures.	The X-ray system creates data for digital exposures in the maxillofacial area and in subareas for dentistry and pediatric dentistry, for hard-tissue diagnostics within ENT medicine, and carpus exposures.

Technological Comparison

Device	**Predicate Device** **Orthophos SL** **(K150217)**	**Proposed Device** **Axeos**
Unit data		
Nominal voltage	200 –240 V	200 –240 V
Permissible deviation	± 10%	± 10%
Rated current	12A	12A
Nominal frequency:	50/ 60 Hz	50/ 60 Hz
Power output of tube assembly	90 kV/12 mA = 1080 W with any radiation time	90 kV/12 mA = 1080 W with any radiation time
Tube voltage	60 – 90kV (for 90 kV max. 12 mA)	60 – 90kV (for 90 kV max. 12 mA)
Tube current	3 – 16 mA (for 16 mA max. 69 kV)	3 – 16 mA (for 16 mA max. 69 kV)
Tube setting 3D	LOW: 6-13mA SD: 7-13 mA HD: 4-12 mA	LOW: 6-13mA SD: 7-13 mA HD: 4-12 mA
Maximum setting range	60 kV / 3 mA to 90 kV / 12 mA	60 kV / 3 mA to 90 kV / 12 mA
Program duration	11.6-23 sec	11.6-23 sec
Exposure time	2.2 - 14.9 sec	2.2 - 16.7 sec
Max. FOV (Size of the presentable anatomical area)	Cylinder with a diameter of approx. 11 cm and a height of approx. 10 cm	Cylinder with a diameter of approx. 17 cm and a height of approx. 13 cm
Slice pitch (voxel size)	80-220µm	80-220µm
Exposure time for a cephalometric image	4.6 - 14.9 sec	4.6 - 14.9 sec
Number of single exposures	SD: 200	SD: 200 up to 361 for Vol 4
	HD: 800	HD: up to 1500, depending on Volume Size

Device	**Predicate Device** **Orthophos SL** **(K150217)**	**Proposed Device** **Axeos**
Total filtration of X-ray tube assembly	> 2,5 AI / 90 IEC 60522 Additional filtration: 0,3 mm Cu for volume VOL 1/2/3 SD and HD exposures 1 mm Cu for volume VOL1/2/3 Low Dose exposures	> 2,5 AI / 90 IEC 60522 Additional filtration 0,3 mm Cu for volume VOL1/2/3 SD and HD exposures 0,5 mm Cu for volume VOL4 SD and HD exposures 1 mm Cu for volume VOL1/2/3/4 Low Dose exposures
Focal spot size acc. to IEC 60336, measured in the central X-ray beam	Nominal focal spot value (f): 0.5 Width (max): 0.75 mm Length (max): 1.10 mm	Nominal focal spot value (f): 0.5 Width (max): 0.75 mm Length (max): 1.10 mm
Imaging programs	Panorama, transverse, cephalometric, 3D, different collimations	Panorama, transverse, cephalometric, 3D, different collimations
X-ray tube	Siemens SR 90/15 FN	Siemens SR 90/15 FN
PAN Sensor	CMOS (Direct Conversion Sensor)	CMOS (Direct Conversion Sensor)
Active sensor area, Pan type:	146 mm x 6 mm	146 mm x 6 mm
Detail resolution	0.1 mm	0.1 mm
Focus-sensor distance	497 mm	497 mm
Digital flat panel 3D	3D Hamamatsu 16x16 Flatpanel with amorphous silicon	3D Hamamatsu 23x16 Flatpanel with amorphous silicon
Active sensor area 3D	160 mm x 160 mm	230 mm x 160 mm
Detail resolution	0.12 mm	0.12 mm
Focus-sensor distance	524 mm	524 mm

Device	**Predicate Device** **Orthophos SL** **(K150217)**	**Proposed Device** **Axeos**
Ceph sensor	Digital CCD line sensor for Ceph exposure technique	Digital CCD line sensor for Ceph exposure technique
Active sensor area,	230 mm x 6.48 mm	230 mm x 6.48 mm
Detail resolution	0.027 mm pixel size	0.027 mm pixel size
Focus-sensor distance	1714 mm	1714 mm
Dose Area Product (DAP)		
Complete range (Ceph, 3D and 2D) Measuring Method A Measuring Method B	 n.a. 1.2 – 3056 mGycm²	 3 – 2199 mGycm² 3 – 3139 mGycm²
Default 3D maximum Measuring Method A Measuring Method B	VOL3/SD/85kV/10mA/4.4s n.a. 781 mGycm²	VOL4/SD/85kV/10mA/5.9s 580 mGycm² 836 mGycm²
Visualization/ Image processing	Uses Sidexis 4 image process software.	Uses Sidexis 4 image process software.
Image reconstruction		
CBCT algorithm	Filtered back-projection	Filtered back-projection
PAN algorithm	Pixel driven back-projection	Pixel drive back-projection
CEPH algorithm	Time delay and integration	Time delay and integration
2D Image types	Different panoramic, bite wing, temporomandibular joint, sinus view..	Different panoramic, bite wing, temporomandibular joint, sinus view
Cephalometric main types	A/P, P/A, Lateral view, Carpus	A/P, P/A, Lateral view, Carpus
Panoramic images	Full frame pan-technology with Autofocus and lingual-buccal exploration.	Full frame pan-technology with Autofocus for Pan images.
3D	Volumes as chosen by the user before the exposure.	Volumes as chosen by the user before the exposure.

Device	**Predicate Device** **Orthophos SL** **(K150217)**	**Proposed Device** **Axeos**
User interface		
Exposure settings	At the operator panel of the device: kV, mA, sec, program, height adjustment, laser locator on/off, rotation of the ring, options.	At the operator panel of the device: kV, mA, sec, program, height adjustment, laser locator on/off, rotation of the ring, options.
Patient fixation	Bite block, chin rest, contact segment for subnasal, supports if necessary.	Bite block, chin rest, contact segment for subnasal, supports if necessary.
	Cephalometer without bite block and chin rest.	Cephalometer without bite block and chin rest.
Localization of exposure area	Given through the geometry of the device and due the help of laser.	Given through the geometry of the device and due the help of laser.
	Additional laser for improvement of mid sagittal head positioning .	Additional laser for improvement of mid sagittal head positioning.
Calibration / Adjustment	Calibration/ adjustment is ensured for sensor (including shading, blemish and gain), geometric, panoramic, volume and Ceph.	Calibration/ adjustment is ensured for sensor (including shading, blemish and gain), geometric, panoramic, volume and Ceph.
	Monthly constancy check	Monthly constancy check

Functional testing as well as performance testing of the proposed device Axeos have been performed to verify that the design outputs meet the design input requirements and to validate that the device conforms to the intended user needs and the intended use as defined.

The comparison of the intended use, the indications for use, as well as of technical and technological characteristics of the subject Axeos with the predicate device Orthophos SL (K150217) supports the substantial equivalence of the proposed device to the predicate device.

7. Non-Clinical Performance Data

Testing to verify the performance requirements of the subject Axeos device was conducted and included in this premarket notification. The results of the performance testing support substantial equivalence.

Tests included in this premarket notification verify the conformity of the proposed Axeos with the requirements of:

- IEC 60601-1: Medical electrical equipment Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- IEC 60825-1: Safety of laser products – Part 1: Equipment classification and requirements.
- IEC 60601-1-3: Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.
- IEC 62366: Medical devices – Application of usability engineering to medical devices.
- ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
- IEC 62304: Medical device software – Software lifecycle processes.
- IEC 60601-2-63: Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment
- IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability, (with third edition of 60601-1)
- Verification activities for confirmation of the image quality of the proposed device has been performed. The results of the image quality review have demonstrated that the device is substantially equivalent to the predicate device.

8. Clinical Performance Data

Given the differences from the predicate device, no human clinical data is necessary to support substantial equivalence.

9. Conclusion Regarding Substantial Equivalence

The information included in this premarket notification supports the substantial equivalence of the subject Axeos. The subject device has the identical intended use as the legally marketed predicate device. The subject device also has the identical indications for use and incorporates the same fundamental technology as the predicate device.

Performance data are included in this premarket notification to demonstrate the performance of the subject Axeos against its design, functional, and safety requirements. The results of the testing included in this premarket notification support a determination of substantial equivalence.