K103711

510(k) Summary
for
Sirona Dental Systems
ORTHOPHOS XG 3D/ Ceph

MAR 2 2 2011

1 SPONSOR

Sirona Dental Systems GmbH
Fabrikstrasse 31
D-64625 Bensheim
Germany
Contact Person: Fritz Kolle
Telephone: 49 6251 16 32 94
Date Prepared: December 14, 2010

2 DEVICE NAME

Proprietary Name:	ORTHOPHOS XG 3D / Ceph
Common/Usual Name:	x-ray, tomography, computed, dental
Classification Name:	Computed tomography x-ray system

3 PREDICATE DEVICES

Sirona GALILEOS (K060892) and Sirona ORTHOPHOS XG^{Plus} DS (K033073)

4 INTENDED USE

The ORTHOPHOS XG 3D/ Ceph is intended to produce two dimensional images and three dimensional volume reconstructions, including partial volumes and selected projections of the dentomaxillofacial areas, for use in planning and diagnostic support. Image acquisition, modes include panoramic X-ray, cephalometric X-ray, specialized tomographic X-ray, and cone beam tomography X-ray. The system can also acquire carpal exposures. The system includes an X-ray source, flat panel X-ray detector, positioning devices, as well as interactive 3D reconstruction, processing, and archiving software.

5 DEVICE DESCRIPTION AND FUNCTION

The ORTHOPHOS XG 3D/ Ceph is a dental computed tomography system intended to produce X-rays for obtaining two dimensional images (panoramic and cephalometric) and three dimensional volume reconstructions of the teeth, jaw, and the head area, which includes dentomaxillofacial areas, for use in planning and diagnostic support.
In 3D mode the OP XG 3D device generates a conical x-ray beam that rotates round the patient's head within a certain angle.

The device comprises a combi sensor with 2D panoramic and cephalometric sensors and a flat panel sensor for 3D volume exposure. Five volume regions are defined by the geometry of the ORTHOPHOS XG 3D/ Ceph. Four class I laser beam light localizers serve for postioning the patient's head that may be fixed through bite block and adjustable forehead and temple supports.

From the obtained exposures in the 3D mode a three dimensional image is reconstructed and can be viewed as well as 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 data base.

An operator control panel allows height adjustment, selection of mode and program and indicates machine states.

A separate handhold push-button serves for exposure release.

An optional remote control is available.

5.1 Scientific Concept

The underlying scientific concept is combining two exposure technologies, panoramic including cephalometric, (2D), and volumetric (3D), in one device. Volumetric exposures are obtained by cone-beam technology.

5.2 Physical and Performance Characteristics

5.2.1 Design

The ORTHOPHOS XG 3D/ Ceph comprises of 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 a combi sensor are fixed to the ring. The combi sensor houses a panoramic and cephalometric line sensor (2D) and a flat panel sensor for volumetric exposures (3D). In 3D mode the OP XG 3D device generates a conical x-ray beam that rotates round the patient's head within a certain angle.
Four class I laser beam light localizers serve for positioning the patient's head that may be fixed through bite block and adjustable forehead and temple supports.

The exposure area is defined by the geometry of the ORTHOPHOS XG 3D/ Ceph.
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.

An optional remote control is available.

The PC software reconstructs the three dimensional image as well as processing 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 data base.

5.2.2 Material Used

Materials that come into patent 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.

6 SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS

The ORTHOPHOS XG 3D/Ceph is a further development of the ORTHOPHOS XG^{Plus} DS / Ceph (K033073) [1] and expands the device capabilities with the 3D function of GALILEOS (K060892).

In 2D mode the ORTHOPHOS XG 3D /Ceph provides the same 2D operating principles and programs as the predicate device ORTHOPHOS XG^{Plus} DS/Ceph.

In 3D mode the ORTHOPHOS XG 3D /Ceph provides an adapted program-subset of the GALILEOS and the same 3D operating principles as the predicate device GALILEOS.

The modified operator panel of the ORTHOPHOS XG^{Plus} DS/Ceph now incorporates the 3D functionality in addition.

In the ORTHOPHOS XG 3D/Ceph a solid state flat panel image receptor replaces the image intensifier of the GALILEOS and is combined in a common housing with image receptors of the ORTHOPHOS XG^{Plus} DS / Ceph. The appropriate sensors are moved in the correct positions automatically according to mode and program selected.

ORTHOPHOS XG 3D/Ceph provides the selection of five volume regions whereas the GALILEOS provides these regions together in one volume.

1 It includes the ORTHOPHOS XG 5DS / Ceph which provides a subset of programs.

The X-ray generator of the ORTHOPHOS XG^{Plus} DS / Ceph has been adapted in order to be capable of 3D scans and to have similar technical characteristics as the GALILEOS generator.
ORTHOPHOS XG 3D/Ceph has a smaller collimator opening in 3D mode compared with GALILEOS (smaller field of view and five volume regions).

An additional class I laser light beam localizer has been added to ORTHOPHOS XG^{Plus} DS / Ceph that in conjunction with another one marks the Field of View in 3D mode.

The PC software performs same functions and algorithms as with the ORTHOPHOS XG^{Plus} DS / Ceph in the 2D mode and GALILEOS in 3D mode. For the 3D mode the software has been adapted to the smaller field of view and the selection for five volume regions.

ORTHOPHOS XG 3D/Ceph offers a calculated panoramic view in combination with slices orthogonal to the panoramic curve ('transversal slices') as predicate GALILEOS.

ORTHOPHOS XG 3D/Ceph offers same functionality in viewing slices, projections and volume views.

7 NONCLINICAL TESTING

The ORTHOPHOS XG 3D/ Ceph system functions have been tested in a system test.

For both modes, 2D and 3D, exposures have been tested utilizing test phantoms. The tests evaluate the equality of exposures of proposed ORTHOPHOS XG 3D/ Ceph and predicate devices ORTHOPHOS XG^{Plus} DS/Ceph and GALILEOS.

For 3D mode additional tests has 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"

8 CLINICAL TESTING

Clinical tests have not been performed.

9 CONCLUSION

Based on a comparison of intended use, indications, construction materials, principal of operations, features and technical data, the Sirona Dental ORTHOPHOS XG 3D /Ceph is safe and effective to perform its intended use as well as substantially equivalent to the Predicate Devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Fritz Kolle
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Sirona Dental System GmbH
Fabrikstrasse 3, D-64625 Bensheim
GERMANY

MAR 2 2 2011

Re: K103711
Trade/Device Name: Orthophos XG 3D/ Ceph
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: December 14, 2010
Received: December 20, 2010

Dear Mr. Kolle:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K103711

Device Name: ORTHOPHOS XG 3D/ Ceph

Indications for Use:

The ORTHOPHOS XG 3D/ Ceph is intended to produce two dimensional images and three dimensional volume reconstructions, including partial volumes and selected projections of the dentomaxillofacial areas, for use in planning and diagnostic support. Image acquisition, modes include panoramic X-ray, cephalometric X-ray, specialized tomographic X-ray, and cone beam tomography X-ray. The system can also acquire carpal exposures. The system includes an X-ray source, flat panel X-ray detector, positioning devices, as well as interactive 3D reconstruction, processing, and archiving software.

Prescription Use ___X___ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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