

OCT 1 0 2003

**510(k) Summary
for
Orthophos XG^{Plus} DS/Ceph Dental X-Ray System**

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstraße 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 3294

Date Prepared: September 26, 2003

2. DEVICE NAME

Proprietary Name: Orthophos XG^{Plus} DS/Ceph
Common/Usual Name: Dental panoramic and cephalometric X-ray system
Classification Name: Extraoral source dental X-ray system

3. PREDICATE DEVICE

Orthophos PLUS DS / PLUS DS Ceph: K013650

4. INTENDED USE

The Orthophos XG^{Plus} DS/Ceph Dental X-Ray System is an extraoral source dental panoramic and optional cephalometric X-ray system intended to produce X-rays for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

5. DEVICE DESCRIPTION

The Orthophos XG^{Plus} DS/Ceph is the neXt Generation in the Orthophos family of digital dental X-ray Systems. Similar to the prior Orthophos PLUS DS/PLUS DS Ceph device, the Orthophos XG^{Plus} DS/Ceph offers digital imaging with or without

the optional cephalometric attachment. Both the new and predicate digital imaging systems offer substantially the same panoramic and optional cephalometric imaging programs with the same exposure levels (kV/mA). Modifications resulting in the new device include a new control panel consisting of an EasyPad with a touchscreen graphical user interface and associated buttons, a new sized CCD sensor, artifact reduction on selected programs, additional options for refining image quality, an electromechanical diaphragm controlled by stepper motors with an adjustable filter system, Class I laser light system for head positioning (replaces halogen light source), and a modified scanning technique for the cephalometric imaging.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The modified device has the same intended use and principles of operation as the prior Orthophos devices, as well as substantially equivalent technical specifications. The modifications were implemented to improve ease of use and image quality, and do not change the intended use or fundamental scientific technology of the device. A hazard analysis, validation testing, and Declaration of Conformity to Design Controls were submitted to support the substantial equivalence of the modified Orthophos system.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2003

Sirona Dental Systems GmbH
% Sheila M. Hemeon-Heyer, JD, RAC
Senior Staff Consultant
Medical Devices Consultants, Inc.
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K033073
Trade/Device Name: Orthophos XG^{Plus} DS/Ceph
Dental X-Ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source
x-ray system
Regulatory Class: II
Product Code: 76 EHD
Dated: September 26, 2003
Received: September 29, 2003

Dear Ms. Hemeon-Heyer:

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 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); 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.

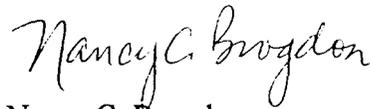
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 033073

Device Name: Orthophos XG^{Plus} DS/Ceph Dental X-Ray System

Indications For Use:

The Orthophos XG^{Plus} DS/Ceph Dental X-Ray System is an extraoral source dental panoramic and optional cephalometric X-ray system intended to produce X-rays for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033073

†

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use