K013650

DEC 0 6 2001

Special 510(k) Summary
for
Orthophos PLUS DS / PLUS DS Ceph

1. SPONSOR

Sirona Dental Systems GmbH
Fabrikstraße 31
D-64625 Bensheim
Germany

Contact Person: Fritz Kolle
Telephone: 49 6251 16 3294

Date Prepared: November 5, 2001

2. DEVICE NAME

Proprietary Name: Orthophos PLUS DS / 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 DS / DS Ceph (K972312)
Orthophos 5 / PLUS / CD (K983057)

4. INTENDED USE

The Orthophos PLUS DS / PLUS DS Ceph is an extraoral source dental 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 PLUS DS / PLUS DS Ceph contains 26 factory installed programs that allow for comprehensive imaging of the entire maxillofacial region. These include panoramic exposures of the teeth, maxillary sinuses and temporal mandibular joints, transverse exposures of the maxillary and mandibular molar, canine and anterior areas, and cephalometric exposures of the skull. This Special 510(k) is being submitted to add the transverse slice imaging programs to the panoramic and cephalometric imaging programs previously described in K972312.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The Orthophos PLUS DS / PLUS DS Ceph that is the subject of this 510(k) premarket notification is a modification of the Orthophos DS / DS Ceph that was previously cleared for marketing under K972312. The modified device has the same intended use and principles of operation as the original device, as well as substantially equivalent technical specifications. The main difference is the addition of the transverse slice imaging capability, which is the same technology as previously reviewed for the Orthophos 5 / PLUS / CD under K983057. The transverse slice exposures generated by the Orthophos PLUS DS / PLUS DS Ceph are processed into digital images by the SIDEXIS Digital Radiography Processing System, while the transverse slice exposures generated by the Orthophos 5 / PLUS / CD are processed into film images. A hazard analysis, validation testing, and Declaration of Conformity to Design Controls were submitted to support the substantial equivalence of the modified Orthophos system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 6 2001

Sirona Dental Systems, Inc.
% Ms. Sheila M. Hemeion-Heyer
Medical Device Consultants
49 Plain Street
NORTH ATTLEBORO MA 02760

Re: K013650
Trade/Device Name: Orthophos PLUS DS/PLUS DS Ceph
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 MUH
Dated: November 5, 2001
Received: November 6, 2001

Dear Ms. Hemeion-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.

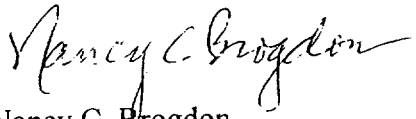
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 this 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" (21 CFR Part 807.97). 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):

Device Name: Orthophos PLUS DS / PLUS DS Ceph

Indications For Use:

The Orthophos PLUS DS / PLUS DS Ceph 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)

David A. Jeyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013650

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)