SEP 12 1997

510(k) Summary

Orthophos Plus and Orthophos Plus/CD

1. Sponsor

Pelton & Crane
A Siemens Company
P.O. Box 7800
Charlotte, NC 28241-7800
Tel: (704) 523-3212
Fax: (704) 523-0002

Contact Person: Duronnie Harrell
Director, Quality Assurance and Regulatory Affairs

Date Prepared: June 12, 1997

2. Device Name

Classification Name: Extraoral source X-ray system, 21 CFR 872.1800, Class II

Proprietary Name: Orthophos Plus and Orthophos Plus/CD

3. Intended Use

The Orthophos Plus and Orthophos Plus/CD are intended to produce X-rays for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The X-ray source is located outside the mouth.

4. Device Description

The Orthophos Plus contains 23 factory installed programs that allow for comprehensive imaging of the entire maxillofacial region. The Orthophos Plus software programs allow for panoramic radiographs of the teeth, maxillary sinuses, and temporal mandibular joints, as well as transverse panoramic tomographs of the lateral, canine and anterior maxillary and mandibular regions. The device is

equipped with various bite block and head positioning accessories. The device is also available with an optional cephalometric attachment (Orthophos Plus/CD).

5. Basis For Substantial Equivalence

The Orthophos Plus and Orthophos Plus/CD are substantially equivalent to the Orthophos and Orthophos C which were cleared for marketing under K895467. The Orthophos Plus is a revised version of the Orthophos and differs from the Orthophos as follows:

(1) Eleven additional programs have been added to the Orthophos Plus to allow for additional views of the maxillofacial regions.

(2) Additional primary and secondary collimators have been added to allow for the transverse slice imaging.

(3) Additional patient head positioning and bite block accessories have been added to allow for the transverse slice imaging.

These technical changes do not alter the intended use of the device, nor do they raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 1997

Pelton & Crane
c/o Sheila Hemeon-Heyer, JD, RAC
Regulatory Services Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K972249
Orthophos Plus and Orthophos Plus/CD
(Dental X-Ray System)
Dated: June 12, 1997
Received: June 16, 1997
Regulatory class: II
21 CFR 872.1800/Procode: 90 EHD

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Orthophos Plus and Orthophos Plus/CD

Indications For Use:

The Orthophos Plus and Orthophos Plus/CD are intended to produce X-rays for dental radiographic examination and diagnosis of diseases of the teeth, jaw, and oral structures. The X-ray source is located outside the mouth. The system provides for panoramic imaging of the entire maxillofacial region as well as transverse slice imaging of the maxillary and mandibular regions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972249

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