MAR 14 2000

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DENTSPLY
GENDEX

GENDEX Dental X-Ray Division
Dentsply International Inc.
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510(k) Summary Statement for the
Gendex Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System

I General Information

Submitter:	Gendex Dental X-Ray Division of Dentsply International, Inc. 901 West Oakton St. Des Plaines, IL 60018
Telephone:	(847) 640-4800 - Company Number (847) 640-4924 - Contact Person
Fax:	(847) 640-4970
Contact Person:	William T. Cousins Area Manager Quality Assurance and Regulatory Affairs
Summary Preparation Date:	December 14, 1999

II Names

Device Name:	Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System
Primary Classification Name:	76EHD - Unit, X-Ray, Extraoral with Timer

III Predicate Devices

- Pelton & Crane Orthophos Plus
- Instrumentarium Imaging Orthorpantomograph® OPD
- Planmeca PM 2002 CC Proline
- Gendex Orthoralix SD2/Ceph & S/Ceph

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IV Product Description

The Dentsply/Gendex Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System is an extraoral source of x-rays for imaging of the dento-maxilofacial area.

The Dentsply/Gendex Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System is comprised of the following main components:

- High frequency inverter which supplies a true DC output and accurate technique factors
- A microprocessor controlled user-friendly electronic control
- A motorized column to be fixed to the wall
- Counter balanced overhead carriage with controls for patient positioning, setting and control of technique factors and radiographic projection geometry
- Cassette drive system with flat cassette for 15x30 cm film
- X-ray tubehead, with DC power supply via electronic converter
- Remote control box and handswitch
- Optional cephalometric arm and head positioner
- Optional utilities for transverse scanography of the jaw ("Transcan®")

During a panoramic exposure, the x-ray tube and cassette holder moves around the patient's head. The beam from the x-ray tube is collimated by a slit diaphragm. The flat film cassette passes behind a secondary collimator which blocks the radiation scattered from the patient. Patient positioning is by means of a bite guide and a headrest. During exposure, the patient, remains still while the motorized components rotate.
All movements for the panoramic radiographic projection are performed by four independent motors, which are microprocessor controlled.

V Indications for Use / Rationale for Substantial Equivalence

The Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System is to be used as an extraoral source of x-rays for imaging of the dento-maxilofacial area.

It shares the same indications for use, similar materials, design, operational, and functional features and therefore is substantially equivalent to the predicate devices listed in section III of this summary.

VI Safety and Effectiveness Information

Safety and Effectiveness is demonstrated by:

- Performance testing to meet product specifications
- Software testing to validate software design / performance
- Effective clinical image exposures
- Hazard analysis including risk level and solution
- Same indications for use as predicate devices.

All the above steps and evaluations combine to demonstrate that the Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System is safe and effective when the device is used as labeled.

VII Conclusion

The Gendex Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System was found to be is Substantially Equivalent to the predicate devices; the Pelton & Crane Orthophos Plus, the Planmeca PM 2002 CC Proline, the Instrumentarium Imaging Orthorpantomograph® OPD, and the Gendex Orthoralix SD2/Ceph and S/Ceph. The Gendex Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System shares the same indications for use, similar materials, design, operational, and functional features as the current marketed predicate devices. It has been shown to be safe and effective when used as labeled.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2000

William T. Cousins
Area Manager, Quality Assurance and Regulatory Affairs
GENDEX Dental X-Ray Division
Dentsply International, Inc.
901 West Oakton Street
Des Plaines, IL 60018-1884

Re: K994285
Orthoralix 9200 (Panoramic and
Cephalometric Dental X-Ray System
Dated: December 14, 1999
Received: December 20, 1999
Regulatory class: II
21 CFR 872.1800/Procode: 76 EHD

Dear Mr. Cousins:

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 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). 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 requirements, 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) 594-4591. 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 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/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known): Not Assigned

Device Name: Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System

Indications for Use:

The Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System is to be used as an extraoral source of x-rays for imaging of the dento-maxilofacial area.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K994285

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

(Optional Format 1-2-96)

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