SEP 2 5 2003

K032355

DENTSPLY
GENDEX

DENTSPLY International
Gendex Division
901 West Oakton Street
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510(k) Summary Statement for the
Gendex Orthoralix 9200 DDE Digital Panoramic and Cephalometric Dental X-Ray System

I. General Information

Submitter:	DENTSPLY International Gendex Division 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:	John R. Miller Director, Quality Assurance and Regulatory Affairs
Summary Preparation Date:	June 30, 2003

II. Names

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

III. Predicate Devices

- Gendex Orthoralix 9200 and 9200 Plus
- Instrumentarium Orthoceph® OC100 D Direct Digital Cephalometric Imaging System
- Planmeca DIMAX2 Direct Digital Imaging System
- Sirona Orthophos Plus DS

IV. Product Description

The DENTSPLY International, Gendex Division Orthoralix 9200 DDE Digital Panoramic and Cephalometric Dental X-Ray System is an extraoral source of x-rays for imaging of the dento-maxilofacial area.

The DENTSPLY International, Gendex Division Orthoralix 9200 DDE Digital 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 postioner
- 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 DDE Digital 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, operations, 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
- Risk 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 DDE Digital Panoramic and Cephalometric Dental X-Ray System is safe and effective when the device is used as labeled

VII. Conclusion

The DENTSPLY International, Gendex Division Orthoralix 9200 DDE Digital Panoramic and Cephalometric Dental X-Ray System was found to be substantially equivalent to the predicate devices, the Gendex Orthoralix 9200 and 9200 Plus, the Instrumentarium Orthoceph® OC100 D Direct Digital Cephalometric Imaging System, the Planmeca DIMAX2 Direct Digital Imaging System, and the Sirona Orthophos Plus DS. The DENTSPLY International, Gendex Division Orthoralix 9200 DDE Digital 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

SEP 2 5 2003

Mr. John R. Miller
Director
DENTSPLY International
Gendex Division
901 West Oakton Street
DES PLAINES IL 60018-1884

Re: K032355
Trade/Device Name: Orthoralix 9200 Panoramic and Cephalometric Dental X-Ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: July 21, 2003
Received: July 30, 2003

Dear Mr. Miller:

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

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

Enclosure

K032355

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

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

Indications for Use:

The Orthoralix 9200 DDE Digital 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)

David R. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K032355

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

(Optional Format 1-2-96)