



GENDEX Dental X-Ray Division
Dentsply International Inc.
901 West Oakton Street
Des Plaines, IL 60018-1884
Phone (847) 640-4800
FAX (847) 640-4970

**510(k) Summary Statement for the
Gendex 765DC Intraoral 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) 640-4908 – Contact Person

Fax: (847) 640-4970

Contact Person: Daniel P. Murphy
Director of Operations

Summary Preparation Date: August 4, 1999

II Names

Device Name: Gendex 765DC
Intraoral Dental X-Ray System

Primary Classification Name: 76EHD – Unit, X-Ray, Extraoral with Timer

III Predicate Devices

- Sirona Heliodent DS
- Planmeca Prostyle Intra
- Gendex GX-DC
- Gendex GX-770

IV Product Description

The Dentsply/Gendex 765DC Intraoral Dental X-Ray System is an extraoral source of x-rays for intraoral images in dental radiography.

The Dentsply/Gendex 765DC Intraoral Dental X-Ray System is comprised of the following main components:

- X-ray tubehead
- Yoke with user interface capabilities
- Articulation arm
- Horizontal arm
- Electronic control unit (which may be mounted remotely)
- Wall mount
- 8" or 20cm cone

Optional components:

- 8 ft. coil cord with exposure switch
- 55" and 65" reach option
- Optional cone lengths and shapes

The power supply is regulated to provide a fixed 65kVp, and the x-ray target current is fixed at 7ma. Predefined exposure times may be selected directly through the control or yoke switchpads. The range of exposure time is 0.02 through 2.00 seconds.

V Indications for Use / Rationale for Substantial Equivalence

The 765DC Intraoral Dental X-Ray System is to be used as an extraoral source of x-rays in Dental Radiography.

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.

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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 765CD Intraoral Dental X-Ray System is safe and effective when the device is used as labeled.

VII Conclusion

The Gendex 765DC Intraoral Dental X-Ray System was found to be is Substantially Equivalent to the predicate devices; the Sirona Heliodent DS, the Planmeca Prostyle Intra, the Gendex GX-770, and the Gendex GX-DC. The Gendex 765DC Intraoral 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.



SEP 7 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Daniel P. Murphy
Director of Operations
GENDEX Dental X-Ray Division
Dentsply International Inc.
901 West Oakton Street
Des Plaines, IL 60018-1884

Re: K992610
Gendex 765DC™
Intraoral Dental X-Ray System
Dated: August 4, 1999
Received: August 4, 1999
Regulatory Class: II (two)
Product Code: 90 EHD
21 CFR 872.1800

Dear Mr. Murphy:

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) 594-4613. 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/dsma/dsmamain.html>".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting 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): Not Assigned

Device Name: Gendex 765DC
Intraoral Dental X-Ray System

Indications for Use:

The Gendex 765DC Intraoral Dental X-Ray System is to be used as an extraoral source of x-rays in Dental Radiography.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

David A. Symon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992610

Prescription Use _____
(Per 21CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)