

K980543

**Attachment 11:
510(k) Summary of Safety and Effectiveness
DenOptix Barrier Envelope**

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

APR 14 1998

Submitter: DENTSPLY International, Inc.
DENTSPLY Gendex
901 West Oakton Street
Des Plaines, IL 60018-1884

Contact Person: Daniel P. Murphy
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Date Prepared: FEBRUARY 9, 1998

Device Name: DenOptix Barrier Envelope

Common Name: Dental Barrier Envelope

Classification Name: Electrostatic X-ray Imaging System, IXK, 892.1630

Predicate Device: Kodak ClinAsept Barrier Envelope, 510(k) K884827

Product Description: The DenOptix Barrier Envelope is a single-use pouch available in sizes corresponding to standard intra-oral imaging plate dimensions. Imaging plates used for intraoral dental x-ray procedures are sealed inside the envelope before being placed into the patient's mouth. The envelope is opaque on one side to protect the imaging plate from ambient light.

Indications for Use: The DenOptix Barrier Envelope is a single-use device intended for use with the DenOptix Digital Imaging System (K955643) to prevent contamination of the phosphor imaging plate with saliva and other bodily fluids.

Rationale for Substantial Equivalence

The DenOptix Barrier Envelope shares the same indications for use as the predicate device. It is manufactured by the same Contract Manufacturer with equivalent materials, manufacturing process, and inspection and test procedures. The difference between the DenOptix Barrier Envelope and the predicate device is the addition of a blue colorant to one side of the envelope in order to provide protection against ambient light. Biocompatibility of materials has been demonstrated.

Safety and Effectiveness Information:

There are no differences between the design or manufacture of the DenOptix Barrier Envelope and the predicate device that could affect effectiveness relative to the intended use. Physical testing was performed to demonstrate performance relative to light protection. Biocompatibility testing was conducted in accordance with ISO 10993.

Conclusion:

The DenOptix Barrier Envelope was found to be substantially equivalent to the predicate device. The DenOptix Barrier Envelope is identical to the predicate device except that the DenOptix Barrier Envelope provides protection from ambient light for phosphor imaging plates through the addition of an opaque colorant to one side of the envelope.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1998

Daniel P. Murphy
Director Engineering,
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Re: K980543
DenOptix™ Barrier Envelope
Dated: January 9, 1998
Received: February 12, 1998
Regulatory class: II
21 CFR 872.1800
Procode: 90 EHD

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 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,

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

Enclosure

