APR 2 9 2004 SOREDEX

510(k) Summary

K033755

Date
November 27, 2003

Submitters Information
Soredex Instrumentarium Corporation
Elimaenkatu 22
00510 Helsinki
Finland
Phone: +358 10 394820
Fax.: +358 9 7015261
Contact: Kai Lanér

Trade Name
Minray

Common Name
Dental X-ray System

Classification
Unit, X-ray, Extraoral with Timer / EHD

Predicate Device
We consider that Minray is substantially equivalent in design, composition and function with Heliodent DS (K960819).

Product Description
Minray is an extraoral source dental x-ray system, which produces dental images on intraoral digital or film image receptors. The x-ray generator operates on high frequency and has an DC output. There are two selectable anode voltages 60 kV and 70 kV. Anode current is constant 7 mA. Exposure time can be selected from 20 ms to 3.2 s.

Intended Use
The Minray dental x-ray system is intended to be used for dental radiographic examinations by producing radiographs of dentition, jaws and other oral structures on intraoral digital or film image receptor media.

Performance data
Verification and validation testing was successfully performed to confirm that Minray corresponds with the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2004

Mr. Kai Lanér
Soredex Instrumentarium Corporation
Elimäenkatu 22 B, Helsinki
P.O. Box 250
00031 Sordex
FINLAND

Re: K033755
Trade/Device Name: Minray 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: March 10, 2004
Received: March 12, 2004

Dear Mr. Lanér

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 such 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

510 (k) NUMBER : K033755

DEVICE NAME : MINRAY

INDICATIONS FOR USE :

The Minray dental x-ray system is indicated for dental radiographic examinations by producing radiographs of dentition, jaws and other oral structures on intra oral film or digital image receptor media.

Prescription Use ✓
(Per 21 CFR 801.109)

David G. Lyons
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033755