K063459

SOREDEX

510(k) Summary

DEC 26 2006

Date
December 14, 2006

Submitters Information
Soredex Palodex Group Oy
Nahkelantie 160
FIN-04300 Tuusula
Finland
Phone: +358 45 78822000
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Contact: Kai Lanér

Trade Name
Cranex Novus

Common Name
Dental panoramic x-ray equipment, digital

Classification
System, X-ray, Extraoral Source, Digital / MUH

Predicate Device
We consider that Cranex Novus is substantially equivalent in design, composition and function with Cranex D (K043307)

Product Description
Cranex Novus is a panoramic extraoral source dental x-ray system, which produces digital images of dentition. Cranex Novus utilizes digital image receptor(CCD). The technique factor settings for panoramic examinations are: 60 kVp or 70 kVp, 7 mA DC and max. 9 s.

Intended Use
The Cranex Novus dental panoramic equipment is indicated for dental radiographic examinations by producing digital radiographs of dentition, TM-joints and other oral structures.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Kai Lanér
Official Correspondent
Soredex Palodex Group Oy
Nahkelantie 160
FIN 00430 Tuusula
FINLAND

DEC 26 2006

Re: K063459
Trade/Device Name: CRANEX NOVUS
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: November 10, 2006
Received: November 15, 2006

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 (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 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 this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known): K063459

Device Name: CRANEX NOVUS

Indications For Use:

The Cranex Novus dental panoramic equipment is indicated for dental radiographic examinations by producing digital radiographs of dentition, TM-joints and other oral structures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lepore

(Division Sign-Off)
Division of Reproductive, Abdominal,
and [illegible]
510(k) Number K063459