K073350
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SOREDEX

510(k) Summary

Date:

July 23, 2007

Manufacturer:

SOREDEX, PaloDEx Group Oy
P.O.Box 148 (Street address: Nahkelantie 160)
FIN-04301 Tuusula, Finland

Tel: +358 45 7882 2000
Fax: +358 45 7882 2506

Contact person: Mr. Jouni Onnela, Tel +358 40 747 2550

DEC 19 2007

United States Sales Representative (U.S. Designated agent):

INSTRUMENTARIUM DENTAL INC.
300 West Edgerton Ave.
Milwaukee, WI 53207 -6025
Tel: +1 414 747 1030, 800 558 6120
Fax: +1 414 481 8665

Contact Person: Mr. Frank Kashinski, Tel +1 414 747 6315

Trade name:

Scanora 3D

Common name:

Dental cone beam 3D x-ray system with dedicated panoramic imaging

Classification name:

Extraoral source X-ray system (21 CFR 872.1800, product code MUH)

Description:

Scanora 3D is a dental cone beam CT for imaging of teeth, jaw and TMJ areas of the skull. In CT mode it generates a pulsed conical x-ray beam during rotation around a patient's head and produces two dimensional images on a flat panel detector. Three dimensional images are then reconstructed and viewed with software. In panoramic mode panoramic and TMJ images can be taken in the classical way on a separate CCD detector.

Intended use:

Scanora 3D is a dental cone beam computed tomography x-ray system intended to image teeth, jaw and TMJ areas of the skull. A flat panel detector is used to acquire 3D images and an optional CCD sensor to acquire panoramic images. The device is operated and used by dentists and other qualified professionals.

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Substantial Equivalence:

We consider Scanora 3D is similar in design, composition and function to the following predicate devices introduced into commercial distribution after May 28, 1976:

Planmeca Promax 3D (K060328, MUH)
i-CAT Scanner (K061284, MUH)

The assesment of characteristics and performance supports substantial equivalence.

Assesment of characteristics and performance:

Scanora 3D has the same technological characteristics as the predicate devices. It has similar x-ray generation, detectors, imaging technique and system footprint to the predicate devices. A non-clinical image quality comparison demonstrated Scanora 3D produces similar image quality to the predicate device. Scanora 3D complies with applicable FDA and FDA recognized performance standards.

SOREDEX
PaloDEx Group Oy, Nahkelantie 160 P.O. Box 148, 04301 Tuusula, FINLAND • TEL +358 45 7882 2000
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SOREDEX, PaloDEx Group Oy
% Mr. Daniel W. Lehtonen
Senior Staff Engineer-Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

DEC 1 9 2007

Re: K073350
Trade/Device Name: Scanora 3D
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: MUH and JAK
Dated: November 27, 2007
Received: November 29, 2007

Dear Mr. Lehtonen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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

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Indications for Use

510(k) Number (if known): _____

Device Name: Scanora 3D

Indications for Use:

Scanora 3D is a dental cone beam computed tomography x-ray system intended to image teeth, jaw and TMJ areas of the skull. A flat panel detector is used to acquire 3D images and an optional CCD sensor to acquire panoramic images. The device is operated and used by dentists and other qualified professionals.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K673350

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