K092591

510(k) Summary

NOV 20 2009

Date:

August 14, 2009

The name of the 510(k) owner:

Instrumentarium Dental, PaloDEx Group Oy
Nahkelantie 160
04300 Tuusula, Finland

Tel: +358 10 270 2000
Fax: +358 9 851 4048

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

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:

Orthopantomograph® OP30

Common name:

Dental panoramic x-ray equipment, digital

Classification name:

System, x-ray, extraoral source, digital (21 CFR 872.1800, product code MUH)

Predicate device:

CRANEX® Novus (K063459, MUH)

Description:

Orthopantomograph® OP30 is an extraoral source dental x-ray equipment, which produces dental panoramic and TMJ images on its digital x-ray image receptor. The technique factor settings are: 66, 70, 73 or 77 kV, 10 mA and max 10 sec.

Intended use:

The Orthopantomograph® OP30 dental panoramic x-ray equipment is indented for dental radiographic examinations by producing digital radiographs of teeth, TM-joints and other oral structures by dentists and other legally qualified professionals.

Technological characteristics:

Orthopantomograph® OP30 is otherwise similar to the predicate device but its tube head can produce more power (70-77 kV, 10 mA) than that of the predicate device (70 kV, 7 mA) and it has a smal touch panel instead of membrane buttons for setting of technique factors.

Substantial Equivalence:

We consider Orthopantomograph® OP30 is as safe, more effective, and performs as well as or better than the predicate device.

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PaloDEx Group Oy, Tuusula, FINLAND

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Jouni Omnela
Regulatory Manager
Instrumentarium Dental, PaloDEx Group Oy
Nahkelantie 160, 04300 Tuusula
FINLAND

NOV 2 0 2009

Re: K092591
Trade/Device Name: Orthopantomograph® OP30
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: August 14, 2009
Received: August 24, 2009

Dear Mr. Omnela:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting 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): K092591

Device Name: Orthopantomograph® OP30

Indications for Use:

The Orthopantomograph® OP30 dental panoramic x-ray equipment is intended for dental radiographic examinations by producing digital radiographs of teeth, TM-joints and other oral structures by dentists and other legally qualified professionals.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 K092591

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