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K081925

510(k) Summary

SEP - 2 2008

Date:

June 26, 2008

Manufacturer:

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

Tel: +358 45 7882 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:

Snapshot

Common name:

Digital intraoral sensor system.

Classification name:

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

Predicate device:

Sigma M, K063837, MUH

Description:

Snapshot is a digital intraoral sensor system that can be connected to a workstation PC via USB connection. The essential function and purpose of the system in a dental clinic is to capture intraoral digital dental x-ray images. The system can be used with general intraoral X-ray units.

Snapshot utilizes existing designs and share parts with the predicate Sigma M sensor. The sensor is the same CMOS sensor as that of the predicate device. USB 2.0 High speed connection is used for image transfer to a PC.

The basic system consists of

- Sensor, which is available in two sizes
- Workstation software
- Sensor holders and hygienic covers

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Intended use:

Snapshot is intended to be used by dentists and other qualified professionals for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

Technological characteristics:

Snapshot has the same sensor design and materials as the predicate device. The terminal unit between the sensor and a PC is smaller in size than that of the predicate device. The energy source is USB from the PC compared to the rechargeable battery of the predicate device. USB 2.0 High speed connection is used for image transfer to the PC compared to wireless image transfer (WLAN) of the predicate device.

Substantial Equivalence:

We consider Snapshot is similar in design, composition and function to the predicate device Sigma M, K063837, MUH.

The comparison of characteristics also by following the guidance document "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" supports substantial equivalence.

As conclusion Snapshot is as safe, as effective, and performs as well as or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 2 2008

Mr. Jouni Onnela
Regulatory Manager
Instrumentarium Dental, PaloDEx Group Oy
Nahkelantie 160
Tuusula, 00430
FINLAND

Re: K081925
Trade/Device Name: Snapshot
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: June 26, 2008
Received: July 7, 2008

Dear Mr. Onnela:

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): K081925

Device Name: Snapshot

Indications for Use:

Snapshot is intended to be used by dentists and other qualified professionals for producing diagnostic x-ray radiographs of dentition, jaws and other oral structures.

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 K081925