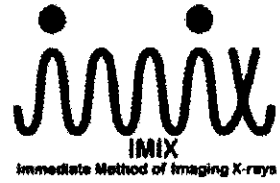
K073114

EXHIBIT 2
510(k) Summary K073114



JAN 17 2008

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Contact: Sigrid Smitt-Jeppesen President and CEO IMIX Americas
Date Prepared: October 31, 2007

1. Identification of the Device:
   Proprietary-Trade Name: IMIX Insight X-Ray Systems
   Classification Name: Stationary X-ray system,
   Product Codes Product Code 90 KPR and MQB
   Common/Usual Name: General purpose diagnostic X-ray Unit.

2. Equivalent legally marketed devices: This notification is for a MODIFIED device. This device COMBINES a 510(k) cleared device, the IMIX Digital Thorax K974863 with 510(k) exempt devices: High Voltage X-Ray Generator, Tubestand, and Table. This combination is functionally identical to a SEDECAL cleared device, Sedecal URS LP X-Ray Units with Digital Detector, K042876. Similar to the Vidar Vision 3000 and Vidar Vision 4000 K071193.

3. Indications for Use (intended use) IMIX Insight X-Ray Systems are indicated for use in generating radiographic images of human anatomy. It has a Solid State X-ray Imaging system intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures. IMIX Insight X-Ray Systems are not indicated for diagnostic X-ray mammography..

4. Description of the Device: System Features
   - URS Radiographic Stand
   - Fully motorized movements with intelligent anti-collision system
   - Automatic settings for 40 and 72 inch SID, auto-position for table exposures
   - Patient Table capacity of 440 lbs
   - Collimator with light field and laser positioning
   - X-Ray Subsystem 65 kW High Frequency Compact Generator
   - Full Anatomical Programming
   - Automatic Exposure Control
   - High Capacity (300kHU) X-ray tube with 0.6/1.2mm focus (27/75kW)
   - Microprocessor System Monitor
   - IMIX Insight Detector: High Resolution 9 megapixel or 16 megapixel CCD detector
   - 40cm x 40cm Image Format (16 x 16 inch)
   - Spatial Resolution: >3.1 lp/mm (4Mp) or >4.3 lp/mm (16Mp)
   - Image Acquisition: 16 bit
   - 3 Field Ionization Chamber

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2008

IMIX ADR Finland OY
% Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K073114
Trade/Device Name: IMIX Insight X-Ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: December 12, 2007
Received: December 19, 2007

Dear Mr. Kamm:

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

Indications for Use

510(k) Number (if known): K073114

Device Name: IMIX Insight X-Ray Systems

Indications For Use:

IMIX Insight X-Ray Systems are indicated for use in generating radiographic images of human anatomy. It has a Solid State X-ray Imaging system intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.
IMIX Insight X-Ray Systems is not indicated for diagnostic X-ray mammography.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073114