

JAN 25 2012

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Contact: Peter Reinli President
Date Prepared: November 11, 2011**

1. Identification of the Device:
Proprietary-Trade Name: PanoRad and PanoRad SL Systems
Classification Name: Stationary X-ray system,
Product Codes Product Codes KPR, MQB, and LLZ
Common/Usual Name: General purpose diagnostic X-ray Units with Digital X-ray receptor panels.
2. Equivalent legally marketed devices: IMIX PanoRad (K101435); This modified system employs the DRTech FLAATZ 560 (K111583), OR the DRTech FLAATZ 750E (K080064) OR Konica Minolta AERO DR (K102349) AND K070618, DICOM Pacs made by O&R. .
3. Indications for Use (intended use) PanoRad and PanoRad SL 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. Not for mammography.
4. Description of the Device: The modified device can produce digital x-ray images in various configurations.

Here is a product configuration matrix:

Product Name	Mechanics	Generator	Detector	Workstation Software
PanoRad	ShinYoung for M Co. SU-1001	CPI CMP 200 or CMP 200DR 50 or 65 kW -OR- Stadler Elektronik 8x Series 50 or 65 kW -OR- EMD Technologies EPS 45-80 Rad FOR ALL MODELS	IMIX ADR OY IMIX 2000 UNV3K or 4K -OR- DRTech FLAATZ 560 (K111583) or FLAATZ 750E (K080064) -OR- AERO DR (K102349 KONICA MINOLTA)	Oehm und Rehbein dicompACS (K070618) An Image Acquisition workstation with DICOM 3 compliance FOR ALL DETECTORS (except Aero DR)
PanoRad SL	ShinYoung for M Co. SU-1001 or SU-3001			

5. Safety and Effectiveness, comparison to predicate device. The results of bench, clinical, and standards testing indicates that the modified device is as safe and effective as the predicate devices. The changed components are in fact identical to the predicate devices.

6. Substantial Equivalence Chart, PanoRad and PanoRad SL Systems

Characteristic	IMIX PanoRad and SomaRad X-Ray Systems, K101435	PanoRad or PanoRad SL X-Ray Systems, Modified device
Intended Use:	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. Not for mammography	SAME
User Interface	Software Driven Touch Panel LCD	Software Driven Touch Panel LCD
Generator	CPI or Stadler	CPI, Stadler, or EMD Technologies
Maximum output	50 and 65 kW	45, 50, 65 or 80 kW
Stand	Supplied by Shinyoung For M Co Ltd	Supplied by Shinyoung For M Co Ltd
Image Acquisition	IMIX or Varian Digital Radiographic Detectors	IMIX ADR OY IMIX 2000 UNV3K or 4K -OR- DRTech FLAATZ 560 (K111583) or FLAATZ 750E (K080064) -OR- AERO DR (K102349)
Digital Panel Size	14" x 17" (4336R) 17" x 17: (4343R) 16" x 16"	Added panels: FLAATZ 750E 14 x 14 FLAATZ 560 14 x 17 AERO DR: 14 x 14 or 14 x 17
Digital Panel Supplier	IMIX panels, same as in K073114 OR: Varian 4343R or 4336R	IMIX panels, DRTech, or Konica Minolta
Digital Resolution	7.9 megapixel or 9.4 megapixel. 139 μ	FLAATZ 750E: 6.6 megapixel 168 μ FLAATZ 560 7.9 megapixel 139 μ AERO DR: 5 megapixel 175 μ
DICOM	Yes, via O&R software cleared in K091364	Yes, via O&R software cleared in K091364
Method of Control	Touch Panel LCD	Touch Panel LCD
Collimator	Ralco R302L/A DHHS	Ralco R302L/A DHHS
Safety	UL listed	UL listed

7. Conclusion: After analyzing bench, clinical, and standards testing data, it is the conclusion of IMIX ADR that the IMIX PanoRad and PanoRad SL X-Ray Systems are as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.



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

IMIX ADR Finland OY
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
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JAN-25-2012

Re: K113855

Trade/Device Name: PanoRad, PanoRad SL X-Ray Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB, LLZ
Dated: December 20, 2011
Received: December 29, 2011

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/cdrh/industry/support/index.html>.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K11 3855

Device Name: PanoRad, PanoRad SL X-Ray Systems

Indications For Use:

IMIX PanoRad and PanoRad SL X-Ray Systems are indicated for use in generating radiographic images of human anatomy. They have Solid State X-ray Imaging systems intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures. (Not for 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 In Vitro Diagnostic Devices (OIVD)

Page 1 of 1

Mary Spald

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K113855