510(k) Summary K102284

This 510k summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

JAN - 3 2010

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Device Name and Classification

Trade name/Product Name:	KrystalRad 560 (FLAATZ 560) System
Classification name:	Stationary X-ray System
Common name:	General purpose diagnostic X-ray System
Classification Panel:	Radiology
Product Code:	MQB
Regulation Number:	892.1680
Date Prepared	December 15, 2010

Substantial Equivalence claimed to: DRTech FLAATZ 750 (K080064)

Device Description

The KrystalRad 560 (FLAATZ 560) System is a flat-panel type digital X-ray detector that captures projection radiographic images in digital format within seconds, eliminating the need for an entire X-ray film or an image plate as an image capture medium. The KrystalRad 560 (FLAATZ 560) device differs from traditional X-ray systems in that, instead of exposing a film and chemically processing it to create a hard copy image, a device called a Detector Panel is used to capture the image in electronic form.

Once the system captures a radiographic image and subsequently displaying and storing an image, radiologists or physicians can adjust the image electronically to optimize the view of the desired anatomy at a work station.

The system enables a user to duplicate images without having to take additional exposures so that the user can easily transmit a duplicate to the second physician who needs the duplicate image through the network.

Hardcopy images can also be made from digital printers, optimizing for the user's preference. The system can have DICOM-compliant output to ensure compatibility with existing imaging network infrastructure.

Indications for Use

The KrystalRad 560 (FLAATZ 560) Digital X-Ray System is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications).

Substantial Equivalence

The KrystalRad 560 (FLAATZ 560) is substantially equivalent to the commercially available DRTech FLAATZ 750 system cleared on January 23, 2010 via 510k K080064. X-ray generation used with the KrystalRad 560 (FLAATZ 560) is identical to the DRTech 750. The KrystalRad 560 (FLAATZ 560) utilizes OmniVision Software while the DRTech FLAATZ 750 system utilizes the proprietary ECOM OmniVue software to control the system and manage digital images collected.

510(k) Number		DRTech Corporation (K080064)	KrystalRad 560 (FLAATZ 560)
Indication for Use		The FLAATZ 750 is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications).	*Same as predicate.*
User Interface		Software Driven Touch Panel LCD + remote control unit + remote console	*Same as predicate.*
Software		ECOM OmniVue	OmniVision FDA cleared via 510k K101315
Design	Panel Shape	Square	Rectangle
	Detector Size	42.9 x 42.9 (cm)	35x43 cm
	Dimensions (W x L x H)	482 x 482 x 35 (mm)	383 X 460 X15mm
	Pixel Pitch	168 (um)	139 um
	Image Size	3072 x 3072 (pixels)	3072 x 2560 pixel
	Selenium Thickness	500 (μm)	500 (μm)
	Weight (Detector)	6.2 (kg)	3.8kg
Materials		Amorphous Selenium (a-Se) Detector	Amorphous Selenium (a-Se)
Performance	DQE	48.5% @ 0.5lp/mm	52.5% @ .5lp/mm
	MTF	78% @ 3.5lp/mm	77% @ 3.5lp/mm
	Resolution	3.6lp/mm	3.5lp/mm

510(k) Number	DRTech Corporation (K080064)	KrystalRad 560 (FLAATZ 560)
Ghosting	<1% @ RQA5 Condition	<1%@RAQ5 conditions
Anatomical Sites	General Radiography	General Radiography
Energy Used and/or Delivered	The Control Box has the following Power Requirement: 100~240V~, 50/60 Hz, Max 2A, Single Phase	The Control Box has the following Power Requirement: 100~240V~, 50/60 Hz, Max 2A, Single Phase

General Safety and Effectiveness Concerns

Electrical, mechanical safety and performance testing according to standard EN/IEC 60601-1, EN/IEC 60601-1-1, EN/IEC 60601-1-3, EN/IEC 60601-2-7, EN/IEC 60601-2-28 and EN/IEC 60601-2-32 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All test results were satisfactory.

Conclusion

The results of all testing demonstrate that the KrystalRad 560 (FLAATZ 560) does not raise any new significant issues of safety, effectiveness or performance of the device when compare to the existing 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

Medicatech USA
% Mr. Daniel Kamm
New Submission Correspondent
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

JAN - 3 2010

Re: K102284
Trade/Device Name: KrystalRad 560 (FLAATZ 560) System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: December 16, 2010
Received: December 21, 2010

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 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

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,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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MEDICAL SYSTEMS

JAN - 3 2010

510(k) Number (if known): K102284

Device Name: KrystalRad 560 (FLAATZ 560) System

Indications For Use:

The KrystalRad 560 (FLAATZ 560) Digital X-Ray Systems is indicated for use in general radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures (excluding fluoroscopic, angiographic, and mammographic applications).

Prescription Use ___X___ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K102284