K111583
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OCT - 4 2011

510(k) Summary

1. Submitter

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2. Contact Person

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3. Date Prepared

March 25, 2011

4. Device Name

FLAATZ 560

5. Reason for Submission

New Device

6. Classification

21 CFR §892.1650

7. Product Code

MQB

8. Predicate Device

KRYSTALRAD 560 (FLAATZ 560) SYSTEM
Medicatech USA,
510(k) No.: K102284

9. Device Description

The FLAATZ 560 is a radiographic image acquisition device. It is a fully integrated image capture and routing system under human operator control. This system may be usable by a technician in a typical radiology environment.

The FLAATZ 560 system includes a Detector Panel, Case, Grid, Control Box, Switch Box, Interconnecting Cables, and API. The Detector Panel is a direct conversion device in the form of a rectangular plate in which the input x-ray photons are absorbed in an a-Se layer. The Control Box functions as a buffer between the Detector Panel and Operating PC while also supplying power to the Detector Panel. The Switch Box transfers signals between the Control Box and X-ray Generator and also indicates the status of the panel using LED lights. Finally, the API contains functions for image data capture and correction of defects on the image data.

10. Intended Use

The FLAATZ 560 is indicated for use in generating 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).

11. Substantial Equivalence

The FLAATZ 560 is substantially equivalent to the KRYSTALRAD 560 (FLAATZ 560) cleared on Jan 3, 2011 via 510k k102284.
Those two systems include same detector, FLAATZ 560, so technological characteristics are equivalent.

Comparison between FLAATZ 560 and KRYSTALRAD 560 (FLAATZ 560) SYSTEM

		FLAATZ 560	KRYSTALRAD 560 (FLAATZ 560) SYSTEM
510(k) Number		Pending	K102284
Indication for Use		The FLAATZ 560 is indicated for use in general radiographic images of human anatomy too. It is the upgraded model of previous FLAATZ 500(K091747), also intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures	Same as predicate
Design	Panel Shape	Rectangular Panel	Rectangular Panel
	Detector Size	353 x 424 (mm)	353 x 424 (mm)
	Dimensions (W x L x H)	383 x 460 x 15 (mm)	383 x 460 x 15 (mm)
	Pixel Pitch	139 x 139 (μm)	139 x 139 (μm)
	Image Size	2,560 x 3,072 (pixels)	2,560 x 3,072 (pixels)
	Se Thickness	500 (μm)	500 (μm)
	Weight (Detector)	3.0(kg)	3.0 (kg)
Materials		Amorphous Selenium (a-Se) Detector	Amorphous Selenium (a-Se) Detector
Performance	DQE	49.3% @ 0.5lp/mm	48.5% @ 0.5 lp/mm
	MTF	78% @ 3lp/mm	78% @ 3lp/mm
	Resolution	3.6 lp/mm	3.6 lp/mm
	Ghosting	<1% @ RQA5 Condition	<1% @ RQA5 Condition
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

		FLAATZ 560	KRYSTALRAD 560 (FLAATZ 560) SYSTEM
Compatibility with Environment and other Devices	EMC	Suitable for EMI and EMS test.	Suitable for EMI and EMS test.
	Operating Temperature	+5 to +35 °C	+5 to +35 °C
	Storage Temperature	+0 to +40 °C	+0 to +40 °C
Electrical Safety		Acceptable electrical safety level.	Acceptable electrical safety level.
Thermal Safety		Acceptable thermal safety level.	Acceptable thermal safety level.
Standards Met		- IEC 60601-1 *Medical electrical equipment – Part 1 : General Requirements for safety.* - IEC 60601-1-2 *Medical electrical equipment – Part 1-2 : General requirements for safety Collateral standard: Electromagnetic compatibility – Requirements and tests*	- IEC 60601-1 *Medical electrical equipment – Part 1 : General Requirements for safety.* - IEC 60601-1-2 *Medical electrical equipment – Part 1-2 : General requirements for safety Collateral standard: Electromagnetic compatibility – Requirements and tests*
Non-clinical test report		Performance test (MTF, DQE, Line Resolution) were done for FLAATZ 560 and the result concludes FLAATZ 560 can display similar images as KRYSTALRAD 560 (FLAATZ 560).	Performance test (MTF, DQE, Line Resolution) were done for FLAATZ 560 and the result concludes FLAATZ 560 can display similar images as KRYSTALRAD 560 (FLAATZ 560).
Clinical test report		Various parts of FLAATZ 560 images were shown to 5 experts and clinical study concludes FLAATZ 560 diagnostic images of equivalent quality as KRYSTALRAD 560 (FLAATZ 560).	Various parts of FLAATZ 560 images were shown to 5 experts and clinical study concludes FLAATZ 560 diagnostic images of equivalent quality as KRYSTALRAD 560 (FLAATZ 560).

12. General Safety and Effectiveness Concerns

The FLAATZ 560 has been evaluated as per FDA's "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices" and has shown good performance, substantially equivalent to the predicate device.

The FLAATZ 560 has also met applicable Electro Magnetic Compatibility (EMC) requirements.

13. Conclusion

The FLAATZ 560 is substantially equivalent to the Predicate Device in design and Performance.

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

DRTECH Corporation
% Mr. Charlie Mack
Principal Engineer
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77325 Joyce Way
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OCT - 4 2011

Re: K111583
Trade/Device Name: FLAATZ 560
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 9, 2011
Received: September 15, 2011

Dear Mr. Mack:

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

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

K111583

Indications for Use Statement

510(k) Number (if known): ~~pending~~ K111583

Device Name: FLAATZ 560

Indications for Use:

The FLAATZ 560 is indicated for use in generating 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S Pastel

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

510K K111583