K111655

NOV 3 0 2011

510(k) Summary

1. Submitter

DRTECH Corporation
333-1 Sangdaewon1-Dong, Seongnam City
Gyeonggi-do, Korea [462-807]
http://drtech.co.kr

2. Contact Person

Choul-Woo Shin
Vice President

cwshin@drtech.co.kr

+ 82-31-730-6823

3. Date Prepared

March 31, 2011

4. Device Name

FLAATZ 760

5. Reason for Submission

New Device

6. Classification

21 CFR §892.1650

7. Product Code

KPR

8. Predicate Device

FLAATZ 750
DRTECH Corp. South Korea
510(k) No.: K080064

9. Device Description

The FLAATZ 760 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 760 system includes a Detector Panel, 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 760 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 760 is substantially equivalent to the FLAATZ 750 cleared on Jan 28 2008 via 510k K080064.

		FLAATZ 760	FLAATZ 750
510(k) Number		Pending	K080064
Indication for Use		The FLAATZ 760 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).	The FLAATZ 750 system generates digital X-ray images that can be used for general X-ray system. The FLAATZ 750 system can interface to traditional X-ray generator and get digital X-ray image. The FLAATZ 750 is intended to be used in same clinical application as traditional film-screen based general radiography system.
Design	Panel Shape	Square Panel	Square Panel
	Detector Size	43 x 43 (cm)	43 x 43 (cm)
	Dimensions (W/L/H)	460 x 460 x 15 (mm)	482 x 482 x 35 (mm)
	Pixel Pitch	168 x 168 (μm)	168 x 168 (μm)
	Image Size	2,560 x 2,560 (pixels)	2,560 x 2,560 (pixels)
	Weight (Detector)	4.6 (kg)	6.2 (kg)
	Fill Factor	83%	83%
Materials		Amorphous Selenium (a-Se) Detector	Amorphous Selenium (a-Se) Detector
Performance	DQE	45.1% @ 0.5lp/mm	40% @ 0.5 lp/mm
	MTF	78% @ 3lp/mm	77.7% @ 3lp/mm
	Resolution	3.0 lp/mm	3.0 lp/mm
	Ghosting	<1% @ RQA5 Condition	<1% @ RQA5 Condition
	Defect Compensation	By Calibration	By Calibration
	Dynamic Range	14bit	14bit
	DICOM Compatibility	DICOM 3.0 Compliant	DICOM 3.0 Compliant
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 760	FLAATZ 750
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.	This is suitable for electrical safety.
Thermal Safety		Acceptable thermal safety level.	This is suitable for thermal safety.
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 760 and the result concludes FLAATZ 760 can display similar images as FLAATZ 750.	Performance test (MTF, DQE, Line Resolution) were done for FLAATZ 750 and the result concludes FLAATZ 760 can display similar images as FLAATZ 750.
Clinical test report		Various parts of FLAATZ 760 images were shown to 5 experts and clinical study concludes FLAATZ 760 diagnostic images of equivalent quality as FLAATZ 750.	Various parts of FLAATZ 750 images were shown to 5 experts and clinical study concludes FLAATZ 760 diagnostic images of equivalent quality as FLAATZ 750.

12. General Safety and Effectiveness Concerns

The FLAATZ 760 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 760 has also met applicable Electro Magnetic Compatibility (EMC) requirements.

13. Conclusion

The FLAATZ 760 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

NOV 3 0 2011

Mr. Choul-woo Shin
Vice President
DRTECH Corporation
333-1 Sangdaewon1-Dong
462-807 SEONGNAM-CITY GYEONGGI-DO
KOREA

Re: K111655
Trade/Device Name: FLAATZ 760
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: KPR
Dated: October 28, 2011
Received: November 4, 2011

Dear Mr. Shin:

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.

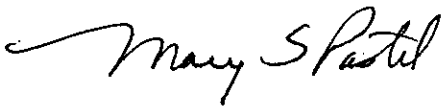
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Statement

510(k) Number (if known): K111655

Device Name: FLAATZ 760

Indications for Use:

The FLAATZ 760 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)

Division of Microbiology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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