K091747

JUL - 1 2009

510(k) Summary

1. Submitter

DRTECH Corporation
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www.drtech.co.kr

2. Contact Person

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3. Date Prepared

May 25, 2009

4. Device Name

FLAATZ 500

5. Reason for Submission

New Device

6. Classification

21 CFR §892.1680

7. Product Code

KPR

8. Predicate Device

FLAATZ 750
DRTECH Corporation
510(k) No.: K080064

9. Device Description

The FLAATZ 500 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 500 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 square 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 500 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. Functional and Safety Testing

The FLAATZ 500 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 500 has also met applicable Electro Magnetic Compatibility (EMC) requirements.

12. Conclusion

The FLAATZ 500 is substantially equivalent to the Predicate Device in design and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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DRTECH Corporation
% Mr. Marc M. Mouser
CAS Manager II/Office Coordinator
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

Re: K091747
Trade/Device Name: FLAATZ 500
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: June 1, 2009
Received: June 16, 2009

Dear Mr. Mouser:

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

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K091747

Device Name: FLAATZ 500

Indications for Use:

The FLAATZ 500 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 Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091747