# 510(k) Summary

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| 1. Submitter | DRTECH Corporation<br>333-1 Sangdaewon1-Dong, Seongnam City<br>Gyeonggi-do, Korea [462-807]<br>www.drtech.co.kr |
| 2. Contact Person | Beom-Jin Moon<br>Vice President<br>bjmoon@drtech.co.kr<br>+ 82-31-730-6804 |
| 3. Date Prepared | December 5, 2007 |
| 4. Device Name | FLAATZ 750 |
| 5. Reason for Submission | New Device |
| 6. Classification | 21 CFR §892.1650 |
| 7. Product Code | MQB |
| 8. Predicate Device | Saturn 9000<br>New Medical Co., LTD.<br>510(k) No.: K063710 |

9. Device Description

The FLAATZ 750 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 750 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 750 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 750 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 750 has also met applicable ElectroMagnetic Compatibility (EMC) requirements.

## 12. Conclusion

The FLAATZ 750 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. Ned Devine
Senior Staff Engineer/Program Reviewer
Underwriters Laboratories, Inc.
333 Pfingsten Road
NORTHBROOK IL 60062

AUG 23 2013

Re: K080064
Trade/Device Name: FLAATZ 750
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: December 20, 2007
Received: January 10, 2008

Dear Mr. Devine:

This letter corrects our substantially equivalent letter of January 23, 2008.

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.

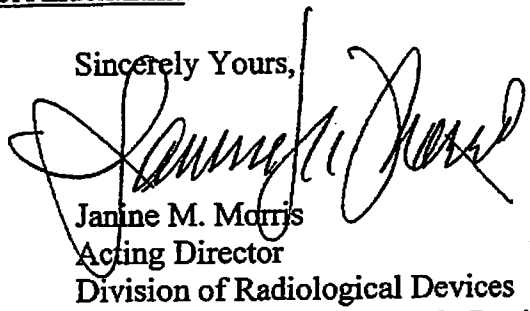
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



Janine M. Morris
Acting 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): K080064

Device Name: FLAATZ 750

Indications for Use:

The FLAATZ 750 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080064