K122842

510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 9 2012

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA. 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Charlemagne Chua
   Manager, Regulatory Affairs
   (714) 730-5000

5. **Date Prepared:**
   September 13, 2012

6. **TRADE NAME(S):**
   RADREX-i, Model No, DRAD-3000E

7. **COMMON NAME:**
   Solid State X-ray Imager (Flat Panel/Digital Imager)

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1650)

9. **PRODUCT CODE / DESCRIPTION:**
   MQB – Solid State X-ray Imager (Flat Panel/Digital Imager)

10. **PERFORMANCE STANDARD:**
    21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

11. **PREDICATE DEVICE:**
    Toshiba RADREX-i (DRAD-3000E), v2.31: K082494
    Toshiba RADREX-i, (DRAD-3000E), v3.0: K083503

12. **REASON FOR SUBMISSION:**
    Modification of a cleared device

13. SUBMISSION TYPE:

Special 510(k)

14. DEVICE DESCRIPTION:

The RADREX-i is a general purpose x-ray system that employs Solid State Imager(s), SSXI, which converts x-rays directly into electrical signals shich can, after appropriate processing be displayed on LCD monitors or printed to a medical grade image printer. The system console is a PC based devise that allows for worklist management, image storage, image processing, image exporting and image printing. The system may be equipped with a table and/or vertical wall unit, is configurable with up to two x-ray tubes, and has an auto stitching function.

15. SUMMARY OF INTENDED USES:

This system is intended for use in conjunction with the ceiling-suspended tube support, high voltage generator, and bucky stand or bucky table incorporating a fixed or detachable (portable) flat panel detector for radiography of the head, chest, abdomen, spine, neck and limbs. This system is used for image acquisition, image display and transmission/output or images to external devices.

16. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the RADREX-i (DRAD-3000E) SW v3.00, K083503, marketed by Toshiba America Medical Systems. The RADREX-i (DRAD-3000E) SW v4.00 includes modifications to the cleared device which adds a new wireless flat panel detector (TFP-4336W, 14 in. x 17 in.) and a new wired flat panel detector (TFP-4343A, 17 in x 17in). The basic system configuration, method of operation, base software and manufacturing process remain unchanged from the cleared device.

17. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 standards and its collateral standards; IEC 60601-2-32 and IEC60601-2-28. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report.

18. TESTING

Image Quality metrics utilizing phantoms are provided in this submission. Additionally, testing of the modified system was conducted in accordance with the applicable standards published by the International Electromechanical Commission (IEC) for Medical Devices and XR Systems.

19. CONCLUSION

The modifications incorporated into the RADREX-i (DRAD-3000E) SW v4.00, do not change the indications for use or the intended use of the device. Safety and effectiveness have been verified via risk management and application of design controls to the modifications.

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

OCT 9 2012

Toshiba Medical Systems Corporation
% Ms. Charlemange Chua
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K122842
Trade/Device Name: RADREX-I (DRAD-3000E, SW v4.0
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: September 14, 2012
Received: September 17, 2012

Dear Ms. Chua:

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
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: RADREX-i (DRAD-3000E), SW v4.0

Indications for Use:

This device is indicated as a general radiography device. It is capable of providing digital images of the head, neck, spine, chest, abdomen, and limbs by converting x-rays to digital images. Excluded indications include mammography, fluoroscopy and angiography studies.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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

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