K123097

510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 13 2013

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:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

5. **TRADE NAME(S):**
   XIDF-DTS801; Dose Tracking System

6. **COMMON NAME:**
   Accessory, System, X-ray Angiography

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

8. **PRODUCT CODE / DESCRIPTION:**
   JAA, Image-intensified fluoroscopic x-ray system.

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

10. **PREDICATE DEVICE:**
    Siemens CAREGRAPH, K982319

11. **REASON FOR SUBMISSION:**
    Modification of a cleared device – INFX-8000F; K081624

12. DEVICE DESCRIPTION:

The dose tracking system (DTS) is an application software package intended to provide the estimated dose distribution information during X-ray fluoroscopic procedures. The dose tracking system (DTS) calculates the radiation dose of the patient's skin using the exposure technique parameters and exposure geometry obtained from the x-ray imaging system (Toshiba Infinix-i) and presents the cumulative results in a color mapping on a 3D graphic of the patient model.

13. SUMMARY OF INTENDED USES:

DTS is intended to display an approximation of both skin dose distribution and skin dose rate in real time during fluoroscopic interventional procedures of cardiac angiography.

This software is intended for use on the Toshiba INFX-8000F CSi cardiac labs.

14. SUBSTANTIAL EQUIVALENCE:

The primary intended use of the devices is to provide the user with estimated dose information being administered to the patient in real time. The methods for calculation and presentation of this information vary. Below is a table that provides similarities and differences.

Company	Toshiba	Siemens
510(k) Control number	Subject device	K982319
Device	DTS (Software)	Caragraph
Intended use	Displaying dose information	Displaying dose information
Combined system	Toshiba Angiography system	Siemens Angiography system
Dose calculation	Reference dose table	Dose area product
Dose map display	Color display on the 3D	Color display on the 2D
Radiation area display	Yes	Yes
Display value		
Cumulative peak skin	Yes	Yes (max. Hot spot)
Dose rate	Yes (Reference point)	No
Fluoro. time	Yes	Yes
Patient information	Yes	Yes
Dose area product	No (X-ray system can display)	Yes
Report function	Yes	Yes

15. 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. 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.

16. SUMMARY OF TESTING:

Testing was performed using anthropomorphic phantoms and Lexan phantoms to verify and validate the performance of the system. Based upon this testing the accuracy of the displayed estimated dose was determined and is included in the user information.

17. CONCLUSION

The additional features that are being added to the INFX-8000F at this time do not change the indication for use or the intended use of the device. Safety and effectiveness have been verified via risk management and application of design controls to this modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 13, 2013

Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems
2441 Michelle Drive
TUSTIN CA 92780

Re: K123097
Trade/Device Name: Dose Tracking System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: February 07, 2013
Received: February 08, 2013

Dear Mr. Biggins:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S for

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): K123097

Device Name: XDIF-DTS801; Dose Tracking Systems

Indications For Use:

DTS is intended to display an approximation of both skin dose distribution and skin dose rate in real time during fluoroscopic interventional procedures of cardiac angiography.

This software is intended for use on the Toshiba INFX-8000F CSi cardiac labs.

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)

Sean M. Boyd -S