



Food and Drug Administration
10903 New Hampshire Avenue
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Toshiba Medical Systems Corporation
% Ms. Janine Reyes
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

June 18, 2015

Re: K150967
Trade/Device Name: XIDF-AWS801, Angio Workstation, V6.10
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: April 13, 2015
Received: April 13, 2015

Dear Ms. Reyes:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent watermark of the FDA logo.

For

Robert Ochs, Ph.D.
Acting 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)

K150967

Device Name

XIDF-AWS801, Angio Workstation, V6.10

Indications for Use (Describe)

The Angio Workstation (XIDF-AWS801) is used in combination with an interventional angiography system (Infinix-i series systems and INFX series systems) to provide 2D and 3D imaging in selective catheter angiography procedures for the whole body (includes heart, chest, abdomen, brain and extremity).

When XIDF-AWS801 is combined with Dose Tracking System (DTS), DTS is used in selective catheter angiography procedures for the heart, chest, abdomen, pelvis, and brain.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. CLASSIFICATION and DEVICE NAME:

Classification Name:	Image-Intensified Fluoroscopic X-Ray System
Regulation Number:	21 CFR 892.1650 (Class II)
Product Code	OWB (Primary), JAA (Secondary)
Trade Proprietary Name:	XIDF-AWS801, Angiography Workstation
Model Number:	XIDF-AWS801 V6.10

2. ESTABLISHMENT REGISTRATION: 9614698

3. CONTACT PERSON, U.S. AGENT and ADDRESS:

Official Correspondent /U.S. Agent:

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Contact Person:

Janine Reyes
Manager, Regulatory Affairs
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jfreyes@tams.com

Establishment Name and Address:

Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, CA 92780

4. MANUFACTURING SITE

Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan
CONTACT: AKINORI HATANAKA

5. Date OF SUBMISSION:

April 13th, 2015

6. PERFORMANCE STANDARD:

21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard

7. PRODUCT CODE:

The Primary Product Code is OWB and the Secondary Product Code is JAA

8. PREDICATE DEVICE:

XIDF-AWS801, Angio Workstation, V5.31 (K142736)

9. REASON FOR SUBMISSION:

Modification of a cleared device

10. SUBMISSION TYPE:

Traditional 510(k)

11. DEVICE DESCRIPTION:

The XIDF-AWS801 Angio Workstation is used for images input from Diagnostic Imaging System and Workstation, image processing and display. The processed images can be outputted to Diagnostic Imaging System and Workstation.

12. SUMMARY OF INTENDED USES:

The Angio Workstation (XIDF-AWS801) is used in combination with an interventional angiography system (Infinix-i series systems and INFX series systems) to provide 2D and 3D imaging of selective catheter angiography procedures for the whole body (includes heart, chest, abdomen, brain and extremity).

When XIDF-AWS801 is combined with Dose Tracking System (DTS), DTS is used with selective catheter angiography procedures for the heart, chest abdomen, pelvis and brain.

13. SUMMARY OF CHANGE(S)

This submission is to report modification of Parametric Imaging Function software application which is meant to provide the user with information that is to be used in adjunct to the normal images provided by the Angio System. Modifications to the cleared device include:

- a. Color Coded Circulation (CCC): Color Coded Circulation creates movies by gradually shifting the color scale to easily understand vessel flow.
- b. Parameters for Imaging:

- i. Time To Arrival (TTA): the period of time required to reach peak contrast enhancement.
- ii. Time To Arrival α (TTA α): Parametric Image created based on the Time To Arrival (TTA) and Peak Height (PH) values for each pixel.
- iii. Mean Transit Time (MTT): The contrast medium residence time.
- iv. Mean Transit Time α (MTT α): Parametric Image created based on the Mean Transit Time (MTT) and Peak Height (PH) values for each pixel.
- v. Time To Peak α (TTP α): Parametric Image created based on the Time To Peak (TTP) and Peak Height (PH) values for each pixel.

Parametric Imaging is intended for use with existing imaging from the cleared device. The software is not intended for stand-alone use or diagnosis.

14. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the XIDF-AWS801, Angio Workstation V5.31 (K142736), marketed by Toshiba America Medical Systems. XIDF-AWS801 (V6.10) includes modifications to the cleared device which includes improvements to the parametric imaging function. Testing was performed using archived clinical images. This testing demonstrated that the implementation of the modifications retained the safety and effectiveness of the cleared device.

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 IEC standards.

16. Testing:

Software verification and validation testing was conducted using archived image data sets. Validation and performance testing objective was to verify Parametric Imaging function correctly calculated and displayed the obtained parameter values, using testing conditions that were representative of clinical conditions using DSA image data.

Validation and performance testing concluded the Parametric Imaging Function correctly calculates and displays the parameter values under clinical conditions. No limitations were observed based on these tests. The results of this testing verified that the performance of the changes was within the specified requirements. Additionally, the testing was used to include user information related to the performance of the changes.

17. Conclusion:

The modifications incorporated into the XIDF-AWS801, V6.10, 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. Testing has verified that that the changes perform as intended.