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

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
U.S. Agent/Director Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

March 11, 2015

Re: K142736
Trade/Device Name: XIDF-AWS801, Angio Workstation, v5.31
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: January 13, 2015
Received: February 18, 2015

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 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142736

Device Name

XIDF-AWS801; Angio Workstation v5.31

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. CLASSIFICATION and DEVICE NAME:

Classification Name:	**Picture archiving and communications system,**
Regulation Number:	**21 CFR 892.1650 (Class II)**
Product Code	**OWB, JAA**
Trade Proprietary Name:	**XIDF-AWS801, Angiography Workstation**
Model Number:	**XIDF-AWS801 V5.31**

2. ESTABLISHMENT REGISTRATION: 9614698

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

Contact/U.S. Agent:
Paul Biggins
Director, Regulatory Affairs
(714) 730-5000
Fax: (714) 730-1310
pbiggins@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:

September 22, 2014

6. PERFORMANCE STANDARD:

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

7. PREDICATE DEVICE:

XIDF-AWS801. Angio Workstation (K141541)

8. REASON FOR SUBMISSION:

Modification of a cleared device

9. SUBMISSION TYPE:

Traditional 510(k)

10. 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.

11. 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 in selective catheter angiography procedure 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 procedure for the heart, chest abdomen, pelvis and brain.

12. SUMMARY OF CHANGE(S)

This submission is to report the addition of several post-processing software applications which are meant to provide the user with information that is to be used in adjunct to the normal images provided by the Angio System. These software packages in Left Atrium Segmentation (automatic segmentation), Parametric Images and MAR (Metal Artifact Reduction) software. All of these features are intended for use with existing imaging from the cleared device. The software are not intended for stand-alone use or diagnosis.

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the XIDF-AWS801, Angio Workstation w/ Dose Tracking System (K141541), marketed by Toshiba America Medical Systems. XIDF-AWS801 (v5.31) includes additional software features. The additional software features have the same intended use as the secondary predicate devices, listed below in table one. Testing was performed using archived clinical images, simulation testing and bench (phantom) testing. This testing demonstrated that the implementation of the modifications retained the safety and effectiveness of the cleared device.

Table 1: Predicate Devices

510(k) Number	Clearance Date	Device Name	Manufacturer
K141541 Primary Predicate	9/8/2014	Angio Workstation v5.31	Toshiba Medical Systems
K132222 Secondary Predicate	11/7/2013	Aquilion ONE Vision	Toshiba Medical Systems
K023760 Secondary Predicate	11/22/2002	Cardiac Functional Analysis Software	Toshiba Medical Systems
K110834 Secondary Predicate	4/26/2011	AW Volume Share 5 with Angio Viz Option	GE Healthcare

14. 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.

15. TESTING

Testing was conducted using bench (phantom) tests, simulations and archived images data sets. 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.

16. CONCLUSION

The modifications incorporated into the XIDF-AWS801, v5.31, 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.