DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

November 25, 2015

Re: K152785
Trade/Device Name: XIDF-AWS801, Angio Workstation, V6.20
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: September 25, 2015
Received: September 25, 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,

Robert Ochs, Ph.D.
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)*
K152785

Device Name

XIDF-AWS801, Angio Workstation, V6.20

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.

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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, JAA**
Trade Proprietary Name:	**XIDF-AWS801, Angiography Workstation**
Model Number:	**XIDF-AWS801, V6.20**

2. ESTABLISHMENT REGISTRATION: 9614698

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

Official Correspondent/U.S. Agent:
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Director, Regulatory Affairs
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Manager, Regulatory Affairs
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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 PREPARED:

September 25, 2015

6. TRADE NAME(S):

XIDF-AWS801, Angio Workstation, V6.20

7. DEVICE CLASSIFICATION:

Class II (per 21 CFR 892.1650)

8. PERFORMANCE STANDARD:

This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard].

9. PREDICATE DEVICE:

XIDF-AWS801, Angio Workstation, V6.10 (K150967)

Product	Marketed by	510(k) Number	Clearance Date
XIDF-AWS801, Angio Workstation, V6.10	Toshiba America Medical Systems	K150967	June 18, 2015

10. REASON FOR SUBMISSION:

Modification of a cleared device

11. SUBMISSION TYPE:

Traditional 510(k)

12. 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.

13. 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.

14. SUMMARY OF CHANGE(S)

This submission is to report the following items have been changed:

a. Dynamic Device Stabilizer function: provides real-time multi-frame image display during live fluoroscopy or DA, which makes a stent appear stationary.

b. 3D-LD image display: 3D-DA performed at low dose. 3D-LD acquisition is intended for use in high-contrast vascular imaging studies such as pediatric pulmonary arteriography and for confirming therapeutic effectiveness immediately after IVR. Note that this technique should not be used for definitive diagnosis or for measurement.

15. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the XIDF-AWS801, Angio Workstation, V6.10 (K150967), marketed by Toshiba America Medical Systems. XIDF-AWS801, Angio Workstation, V6.20, includes modifications to the cleared device consisting of the addition of Dynamic Device Stabilizer function and 3D-LD image display. Testing was conducted using bench (phantom) tests, simulations and archived image data sets. This testing demonstrated that the implementation of the modifications retained the safety and effectiveness of the cleared device.

The basic system configuration, method of operation, base software and manufacturing process remain unchanged from the cleared device. There are no new indications for use or intended use of the device.

16. 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.

17. TESTING:

This submission contains test data that demonstrates that the system modifications result in performance that is equal to or better than the predicate system. 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.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document” issued on May 11, 2005, is also included as part of 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.

18. CONCLUSION

The subject device is substantially equivalent to the XIDF-AWS801, Angio Workstation, V6.10, which was cleared via Pre-Market Notification 510(k), K150967 (See TAB 1). The modifications incorporated into the XIDF-AWS801, Angio Workstation, V6.20, 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.