



Food and Drug Administration
10903 New Hampshire Avenue
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September 8, 2014

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

Re: K141541

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: JAA
Dated: June 9, 2014
Received: June 10, 2014

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,



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)

K141541

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 INFEX 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	JAA – Image Processing/WorkStation
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:

June 9, 2014

6. PERFORMANCE STANDARD:

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

7. PREDICATE DEVICE:

XIDF-AWS801. Angio Workstation (K132106)

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)

Dose Tracking Software has been expanded to provide estimated skin dose for the head. Additionally, the software has been improved over the previous versions to allow simultaneous tracking of dual tubes in bi-plane and dual plane operations.

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the XIDF-AWS801, Angio Workstation w/Dose Tracking System (K132106), marketed by Toshiba America Medical Systems. XIDF-AWS801 (v5.31) includes modifications to the cleared device which includes improvements to the Dose Tracking System. Testing, which conforms to the testing of the predicate device, has been performed to verify the additions to the software do not affect the effectiveness of the performance. This software is a dose management tool and as such does not provided an indicated use. The intended use of the device and predicate remain the same, to provide an estimated skin dose in real time during angiography procedures.

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 has been performed using commercially available phantom and measurement tools. The testing was performed to verify the estimated dose displayed by the software with the actual measured dose on the phantom within the gantry field of exposure.

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.