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

October 30, 2017

Re: K172646
Trade/Device Name: XIDF-AWS801, Angio Workstation, V7.0
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: August 31, 2017
Received: September 1, 2017

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 (DICE) 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 (DICE) 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,

Michael D. O'Hara For

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172646

Device Name
XIDF-AWS801, Angio Workstation, V7.0

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92

1. **CLASSIFICATION and DEVICE NAME**

Classification Name	**Solid State X-ray System, Interventional**
Regulation Number	**21 CFR 892.1650 (Class II)**
Product Code	**OWB, JAA**
Trade Proprietary Name	**XIDF-AWS801, Angio Workstation**
Model Number	**XIDF-AWS801, V7.0**

2. **SUBMITTER'S NAME**

Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
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3. **OFFICIAL CORRESPONDENT**

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5. **MANUFACTURING SITE**

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

6. **ESTABLISHMENT REGISTRATION**

9614698

7. **DATE PREPARED**

August 31, 2017

8. **TRADE NAME(S)**

   XIDF-AWS801, Angio Workstation, V7.0

9. **CLASSIFICATION PANEL**

   Radiology

10. **DEVICE CLASSIFICATION**

    Class II (per 21 CFR 892.1650)

11. **PRODUCT CODE / DESCRIPTION**

    Product Code: OWB, JAA

12. **PERFORMANCE STANDARD**

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

13. **PREDICATE DEVICE**

    XIDF-AWS801, Angio Workstation, V6.20 (K152785)

Product	Marketed by	510(k) Number	Clearance Date
XIDF-AWS801, Angio Workstation, V6.20	Toshiba America Medical Systems	K152785	November 25, 2015

14. **REASON FOR SUBMISSION**

    Modification of a cleared device

15. **SUBMISSION TYPE**

    Traditional 510(k)

16. **DEVICE DESCRIPTION**

    The XIDF-AWS801, Angio Workstation, V7.0 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.

17. **INDICATIONS FOR USE**

    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.

18. **SUMMARY OF CHANGE(S)**

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

    - **PC, GPU, HUB, Monitor:** changed for XIDF-AWS801/B1
    - **Supplemental Symbol:** addition of /B2 model (XIDF-AWS801/B2)
    - **Software change from V6.20 to V7.0:**
        - **LCI image quality improvement:** Implementation of pulse width modulation during 3D reconstruction. This function has been migrated from INFX-8000V,

previously cleared under K162614.

- **Clinical analysis application IV-LINQ (OCT/IVUS integration module):** Images from IVUS or OCT can be imported and used under the supervision of a cardiologist or radiologist to facilitate enhanced stent visualization and measure stent dimensions. OCT/IVUS Integration module (IV-LINQ) is added to CAAS Workstation by Pie Medical Imaging B.V., previously cleared under K151780.
- **Dynamic Device Stabilizer improvement**
- **DTS (Dose Tracking System) improvement**
- **3D Calibration improvement**
- **Serviceability improvement**
- **Renewal of 3D Road Map and 3D Viewer**
- **Provisions of 3D 3D/CBCT artifact (RFC [Ring free correction] / BHC [Beam hardening correction])**
- **Workflow Improvements:**
  - Measurement and segmentation may be performed on 3D-WS
  - Multiple data (volume, object) and analysis results provided by clinical applications are available on 3D-RM application
  - Ease to define working angles

- **Security Kit for DoD:** the Security Kit for DoD (software) is available for XIDF-AWS801/B1. This kit is to meet the security requirement of the U.S. Department of Defense.
- **Cerebral Aneurysm Analysis:** this application is intended to facilitate the extraction and segmentation of user identified aneurysms on the cerebral arteries. The software can be used as an adjunct to diagnosis for the purposes of measurement of size and aspect ratio. Main software of Cerebral Aneurysm Analysis is introduced from Vitrea Software Toshiba Package, VSTP-001A, previously cleared under K151091. The following items are newly added for this software:
  - Communication with Angio Workstation 3D viewer (image data, image storage condition, etc.)
  - Communication with Infinix-i Interventional Angiography systems (3D image angle, etc.)
- **Two dimensional data (512 x 512 x 12/16 bits)** inputs are available for 3D reconstruction

19. 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. 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.

LIST OF APPLICABLE STANDARDS

- IEC60601-1-2:2007
- IEC62304:2006
- IEC62366:2007
- IEC60950-1:2005
- ISO 14971:2007

20. 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. Software modules were subject to verification and/or validation testing to ensure that they were properly integrated into the existing software platform. Additionally, the design controls used for this device included risk management and all known risks were mitigated to an acceptable level.

21. SUBSTANTIAL EQUIVALENCE

This device is substantially equivalent to the XIDF-AWS801, Angio Workstation, V6.20 (K152785), marketed by Toshiba America Medical Systems. XIDF-AWS801, Angio Workstation, V7.0, includes modifications to the cleared device consisting of software change from V6.20 to V7.0, addition of supplemental symbol /B2 model (XIDF-AWS801/B2), two dimensional data (512 x 512 x 12/16bits) inputs are available for 3D reconstruction, clinical analysis application IV-LINQ (OCT/IVUS integration module) and Cerebral Aneurysm Analysis application.

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.

22. CONCLUSION

The subject device is substantially equivalent to the XIDF-AWS801, Angio Workstation, V6.20, which was cleared via Pre-Market Notification 510(k), K152785. XIDF-AWS801, Angio Workstation, V7.0 has the same Indications for Use as the predicate and neither the modifications nor the labeling introduce new intended use. The subject device has new technological characteristics (see Section No. 18 – Summary of Changes). These different technological characteristics raise the same questions of safety and effectiveness including questions of image quality, computed data accuracy, and system reliability. These questions of safety and effectiveness are addressed through design controls and software verification and validation testing which demonstrated that the subject device is substantially equivalent to the XIDF-AWS801, Angio Workstation, V6.20.