Canon Medical Systems Corporation
% Janine Reyes
Manager, Regulatory Affairs
Canon Medical Systems USA
2441 Michelle Drive
TUSTIN, CA 92780

September 10, 2018

Re: K181415
Trade/Device Name: XIDF - AWS801, Angio Workstation (Alphenix Workstation), V8.0
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: August 22, 2018
Received: August 23, 2018

Dear Janine 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

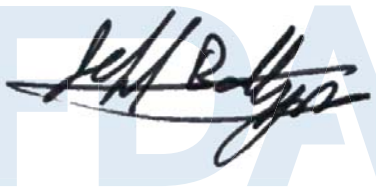
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



for
Robert A. 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)*
K181415

Device Name

XIDF-AWS801, Angio Workstation (Alphenix Workstation), V8.0

Indications for Use *(Describe)*

The Angio Workstation (XIDF-AWS801) is used in combination with an interventional angiography system (Alphenix series systems, 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.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

CANON MEDICAL SYSTEMS USA, INC.

Made For life

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 (Alphenix Workstation)**
Model Number	**XIDF-AWS801, V8.0**

2. **SUBMITTER'S NAME**

Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-Shi, Tochigi-ken, Japan 324-8550

3. **OFFICIAL CORRESPONDENT**

Naofumi Watanabe
Senior Manager, Regulatory Affairs and Vigilance

4. **CONTACT PERSON, U.S. AGENT and ADDRESS**

Contact Person
Janine F. Reyes
Manager, Regulatory Affairs
Canon Medical Systems USA
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 669-7853
Fax: (714) 730-1310
jfreyes@us.medical.canon

Official Correspondent/U.S. Agent
Paul Biggins
Sr. Director, Regulatory Affairs
Canon Medical Systems USA
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 669-7808
Fax: (714) 730-1310
pbiggins@us.medical.canon

5. **MANUFACTURING SITE**

Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

6. **ESTABLISHMENT REGISTRATION**

9614698

7. **DATE PREPARED**

August 20, 2018

8. **TRADE NAME(S)**

XIDF-AWS801, Angio Workstation (Alphenix Workstation), V8.0

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, V7.0 (K172646)

Product	**XIDF-AWS801, Angio Workstation, V7.0**	**XIDF-AWS801, Angio Workstation (Alphenix Workstation), V8.0**
Marketed by	Canon Medical Systems USA	Canon Medical Systems USA
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.	The Angio Workstation (XIDF-AWS801) is used in combination with an interventional angiography system (**Alphenix series systems**, 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.
510(k) Number	K172646	
Clearance Date	October 30, 2017	

14. REASON FOR SUBMISSION

Modification of a cleared device

15. SUBMISSION TYPE

Traditional 510(k)

16. DEVICE DESCRIPTION

The **XIDF-AWS801, Angio Workstation (Alphenix Workstation), V8.0** 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 (Alphenix series systems, 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:

- **BP Auto Angle Support:** supports the planning of bi-plane arm angle without any collision by using 3D volume on 3D viewer at AWS. Once each angle is found, INFX system performs automatic positioning by these angles.
- **Needle Guidance Function Oblique View:** addition of oblique cross-section view within the Needle Guide 3D viewer.
- **CAA (Cerebral Aneurysm Analysis) Vessel Track:** modification to existing CAA (Cerebral Aneurysm Analysis) tool provides the vessel extraction and the virtual stent display feature.
- **3D Viewer Kit:** the existing 3D Viewer software function has been made optional by way of the 3D Viewer kit.
- **Indications For Use:** Indications for use statement was modified to include the Alphenix series systems marketing name.
- **AlphaCT (3D acquisition) Artifact Reduction:** the following modifications have been implemented to reduce artifacts within AlphaCT (3D acquisition) reconstructed images:
  - New RFC parameters
  - New scattered radiation correction parameters for abdominal images
- **Application of the spatial filter to reconstructed images in AlphaCT Device acquisition:** in order to improve stent visualization in AlphaCT Device acquisition, a spatial filter of 11 × 11 pixels is applied to reconstructed slice images in the axial direction.

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

- IEC60601-1-2:2014
- IEC62304:2006 + A1:2015
- IEC62366:2007 + A1:2014
- IEC60950-1:2005 + A1:2009, A2:2013
- 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.

Risk analysis and verification/validation testing, conducted through bench testing, are included in this submission which demonstrates that the requirements for the modifications made to the system have been met. Additionally, Image Quality metrics utilizing phantom image evaluations were employed in bench testing which demonstrates that the requirements for the modifications made to the system have been met.

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

The **XIDF-AWS801, Angio Workstation (Alphenix Workstation), V8.0** is substantially equivalent to the XIDF-AWS801, Angio Workstation, V7.0, which received premarket clearance under K172646, marketed by Canon Medical Systems. XIDF-AWS801, Angio Workstation (Alphenix Workstation), V8.0, includes modifications to the cleared device consisting of software change from V7.0 to V8.0, BP Auto Angle Support, Needle Guide Oblique View, CAA (Cerebral Aneurysm Analysis) Vessel Track, 3D Viewer Kit, AlphaCT (3D acquisition) artifact reduction, application of the spatial filter to reconstructed images in AlphaCT Device acquisition, addition of the Alphenix marketing name to the Indications For Use statement.

The basic system configuration, method of operation, base software and manufacturing process remain unchanged from the cleared device.

22. CONCLUSION

The **XIDF-AWS801, Angio Workstation (Alphenix Workstation), V8.0** performs in a manner similar to and is intended for the same use as the predicate device, as indicated in product labeling. Based upon this information, conformance to standards, successful completion of software validation, application of risk management and design controls and the performance data presented in this submission it is concluded that the subject device is substantially equivalent in safety and effectiveness to the predicate device.