September 27, 2022

Canon Medical Systems Corporation
% Paul Biggins
U.S. Agent/Senior Director Regulatory Affairs
Canon Medical Systems USA
2441 Michelle Drive
TUSTIN CA 92780

Re: K220342
Trade/Device Name: XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.3
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: August 25, 2022
Received: August 29, 2022

Dear Paul 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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)*
K220342

Device Name
XIDF-AWS801, Angio Workstation, (Alphenix Workstation), V9.3

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.

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K220342 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, V9.3**

2. **SUBMITTER'S NAME**

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

3. **OFFICIAL CORRESPONDENT**

Fumiaki Teshima
Senior Manager, Quality Assurance Department

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

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**

February 03, 2022

8. **TRADE NAME(S)**

XIDF-AWS801, Angio Workstation, (Alphenix Workstation), V9.3

9. **CLASSIFICATION PANEL**

Radiology

10. **DEVICE CLASSIFICATION**

Class II (per 21 CFR 892.1650)

CANON MEDICAL SYSTEMS USA, INC.

Made For life

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 **(**Alphenix Workstation**)**, V8.0 (K181415)

Product	**XIDF-AWS801, Angio Workstation (Alphenix Workstation), V8.0**	**XIDF-AWS801, Angio Workstation, (Alphenix Workstation), V9.3**
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 (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.	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	K181415	
Clearance Date	September 10, 2018	

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), V9.3** 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, Workstation and/or other PACS devices. The XIDF-AWS801 provides the image information and measurement results that are required when performing Angiography procedures.

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:

- **Dynamic Device Stabilization (DDS) software** has been improved and new GPU for image processing is included.
- **Windows 10** new OS system is available
- **Embolization Planning software** has been migrated from the INFX platform
- **CAAS Workstation** has been updated with **vFFR application**
- **3D Viewer Software** has been updated to include new functions.
- **4D CT improvement** was migrated from 4DCT that allows user to superimpose CT image on Angiographic image
- **Needle Guidance** was improved which allows up to 5 needles
- **Usability improvements are included in this software**

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
- IEC62366-1:2015 + A1:2020
- IEC62368-1:2014
- 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

The **XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.3** is substantially equivalent to the XIDF-AWS801, Angio Workstation, V8.0, which received premarket clearance under K181415, marketed by Canon Medical Systems. XIDF-AWS801, Angio Workstation (Alphenix

Workstation), V9.3, includes modifications to the cleared device consisting of software change from V8.0 to V9.3.

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), V9.3** 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.