September 12, 2023

Canon Medical Systems Corporation
% Orlando Tadeo
Senior Manager, Regulatory Affairs
Canon Medical Systems USA, INC.
2441 Michelle Drive
TUSTIN CA 92780

Re: K232526
Trade/Device Name: XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA
Dated: August 18, 2023
Received: August 21, 2023

Dear Orlando Tadeo:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
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OHT8: Office of Radiological Health
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232526

Device Name
XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5

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.

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CANON MEDICAL SYSTEMS USA, INC.

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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	**Image-intensified fluoroscopic x-ray system**
Product Code	**OWB, JAA**
Regulation Number	**21 CFR 892.1650**
Regulatory Class	**Class II**
Trade Proprietary Name	**XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5**

2. SUBMITTER'S NAME

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3. OFFICIAL CORRESPONDENT

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

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5. MANUFACTURING SITE

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6. ESTABLISHMENT REGISTRATION

9614698

7. DATE PREPARED

August 18, 2023

8. TRADE NAME(S)

XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5

9. DEVICE NAME

XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5

10. CLASSIFICATION PANEL

Radiology

11. DEVICE CLASSIFICATION

Class II (per 21 CFR 892.1650)

12. PRODUCT CODE / DESCRIPTION

Product Code: OWB – Interventional Fluoroscopic X-Ray System

13. PERFORMANCE STANDARD

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

14. PREDICATE DEVICE

XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.3 (K220342)

TABLE 1: Predicate Device

Trade Proprietary Name	**XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.3**
Marketed by	**Canon Medical Systems USA, Inc.**
510(k) Number	**K220342**
Clearance Date	**September 27, 2022**
Classification Name	**Image-intensified fluoroscopic x-ray system**
Product Code	**OWB, JAA**
Regulation Number	**21 CFR 892.1650**
Regulatory Class	**Class II**

15. REASON FOR SUBMISSION

Modification of a cleared device

16. SUBMISSION TYPE

Special 510(k)

17. DEVICE DESCRIPTION

The **XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5** 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.

18. 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.

19. SUMMARY OF CHANGE(S)

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

Summary of Software Changes:

- **Dynamic Device Stabilizer (DDS)** software with deep learning is changed to improve the detection rate of the stent marker.
  *Note: This item is the target of this submission.

Summary of other software changes since K220342:

- Software in the Angio Workstation was changed from V9.3 to V9.5 via Internal Documentation
  - Electronic licenses for TAVR and CAAS
  - Support of CT DICOM
  - Support of View from foot
  - DTS patient model selection improvement
  - 3D roadmap improvement
  - Serviceability improvement (Smart Update)

20. 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 + A1:2020
- IEC62304:2006 + A1:2015
- IEC 62366-1:2015 + A1:2020
- IEC 81001-5-1:2021
- IEC 62368-1:2014
- ISO 14971:2007

21. TESTING

Risk analysis and verification/validation testing conducted through bench testing demonstrate that the established specifications for the device have been met. Testing was conducted to verify the fixed display performance was improved in V9.5 algorithm compared to V9.3 algorithm for Dynamic Device Stabilizer (DDS) in **XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5**.

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.

A Basic Documentation Level was determined, per the FDA guidance document, "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, is also included as part of this submission.

Additionally, the design controls used for this device included risk management and all known risks were mitigated to an acceptable level.

22. SUBSTANTIAL EQUIVALENCE

The **XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5** is substantially equivalent to the XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.3, which received premarket clearance under K220342, marketed by Canon Medical Systems. XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5, includes modifications to the cleared device consisting of software changes from V9.3 to V9.5.

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 uses of the device.

23. CONCLUSION

The **XIDF-AWS801, Angio Workstation (Alphenix Workstation), V9.5**, performs in a manner similar to and is intended for the same use as the predicate device, as indicated in product the labeling. The modifications incorporated do not change the indications for use or the intended use of the device. 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. It is the contention of Canon Medical Systems Corporation that all new safety issues have been addressed in the design of this change and that adequate evidence of this is presented with this submission.