August 30, 2024

Canon Medical Systems Corporation
℅ Orlando Tadeo Jr.
Sr. Manager, Regulatory Affairs
Canon Medical Systems, USA
2441 Michelle Drive
TUSTIN, CA 92780

Re: K233107
Trade/Device Name: Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: August 2, 2024
Received: August 2, 2024

Dear Orlando Tadeo Jr.:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233107

Device Name
Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5

Indications for Use *(Describe)*
This device is a digital radiography/fluoroscopy system used in a diagnostic and interventional angiography configuration. The system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen, and lower extremities.

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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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**
Regulation Number	**21 CFR 892.1650**
Regulatory Class	**Class II**
Trade Proprietary Name	**Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5**

2. SUBMITTER'S NAME

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

3. OFFICIAL CORRESPONDENT

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

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5. MANUFACTURING SITE

Canon Medical Systems Corporation (CMSC)
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Otawara-shi, Tochigi 324-8550, Japan

6. ESTABLISHMENT REGISTRATION

9614698

7. DATE PREPARED

September 26, 2023

8. TRADE NAME(S)

Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5

9. DEVICE NAME

Interventional Fluoroscopic X-ray System

10. CLASSIFICATION PANEL

Radiology

11. DEVICE CLASSIFICATION

Class II (per 21 CFR 892.1650)

12. PRODUCT CODE / DESCRIPTION

Product Code: OWB – Image-Intensified 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

Alphenix, INFX-8000V/B, INFX-8000V/S, V9.1 (K203551)

TABLE 1: Predicate Device

Trade Proprietary Name	**Alphenix, INFX-8000V/B, INFX-8000V/S, V9.1**
Marketed by	**Canon Medical Systems USA, Inc.**
510(k) Number	**K203551**
Clearance Date	**December 18, 2020**
Classification Name	**Image-Intensified Fluoroscopic X-ray System**
Product Code	**OWB**
Regulation Number	**21 CFR 892.1650**
Regulatory Class	**Class II**

15. REASON FOR SUBMISSION

Modification of a cleared device

16. SUBMISSION TYPE

Traditional 510(k)

17. DEVICE DESCRIPTION

The **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5**, is an X-ray system that is capable of radiographic and fluoroscopic studies and is used in an interventional setting. The system consists of a C-arm/Ω-arm which is equipped with an X-ray tube, beam limiter and X-ray receptor, X-ray controller, computers with system and processing software, and a patient radiographic table.

18. INDICATIONS FOR USE

This device is a digital radiography/fluoroscopy system used in a diagnostic and interventional angiography configuration. The system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities.

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, its collateral standards and particular standards; IEC 60601-2-43, IEC60601-2-28, and IEC TR 60601-4-2. 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

- IEC 60601-1:2005+A1:2012+A2:2020
- IEC 60601-1-2:2014 + A1:2020
- IEC 60601-1-3:2008+A1:2013+A2:2021
- IEC 60601-1-6:2010+A1:2013+A2:2020
- IEC 60601-2-28:2017
- IEC 60601-2-43:2010+A1:2017+A2:2019
- IEC 62304:2006+A1:2015
- IEC 62366-1:2015 + A1:2020
- IEC 81001-5-1:2021
- ISO 17664-2:2021
- IEC TR 60601-4-2:2016

20. TESTING

Risk analysis and verification/validation testing conducted through bench testing demonstrate that the established specifications for the device have been met. 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.

21. SUBSTANTIAL EQUIVALENCE

The **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5** is substantially equivalent to the Alphenix, INFX-8000V/B, INFX-8000V/S, V9.1, which received premarket clearance under K203551, marketed by Canon Medical Systems. **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5**, includes modifications to the cleared device consisting of software changes from V9.1 to V9.5, integrating previously cleared functions/components.

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.

22. CONCLUSION

The **Alphenix, INFX-8000V/B, INFX-8000V/S, 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 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.