October 10, 2025

Canon Medical Systems Corporation
℅ Jonathan Toy
Manager, Regulatory Affairs
Canon Medical Systems, USA
2441 Michelle Drive
TUSTIN, CA 92780

Re: K251602
Trade/Device Name: Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: August 28, 2025
Received: August 28, 2025

Dear Jonathan Toy:

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 Radiologic 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)*
K251602

Device Name
Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging

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.

αEvolve Imaging is an imaging chain intended for adults, with Artificial Intelligence Denoising (AID) designed to reduce noise in real-time fluoroscopic images and signal enhancement algorithm, Multi Frequency Processing (MFP).

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) substantial equivalence information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92

1. **SUBMITTER'S NAME**
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4. **MANUFACTURING SITE**
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5. **ESTABLISHMENT REGISTRATION**
   9614698

6. **DATE PREPARED**
   May 27, 2025

7. **TRADE NAME(S)**
   Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging

8. **COMMON NAME**
   Interventional Fluoroscopic X-ray System

9. **CLASSIFICATION PANEL**
   Radiology

**10. DEVICE CLASSIFICATION**

a) Classification Name: Image-Intensified Fluoroscopic X-ray System
b) Regulation Number: 21 CFR 892.1650
c) Regulation Class: Class II

**11. PRODUCT CODE**

OWB

**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**

| | |
|---|---|
| **Trade Name** | **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5** |
| **Marketed by** | **Canon Medical Systems USA, Inc.** |
| **510(k) Number** | **K233107** |
| **Clearance Date** | **August 30, 2024** |
| **Common Name** | **Interventional Fluoroscopic X-ray System** |
| **Classification Name** | **Image-Intensified Fluoroscopic X-ray System** |
| **Regulation Number** | **21 CFR 892.1650** |
| **Regulation Class** | **Class II** |
| **Product Code** | **OWB** |

**14. REASON FOR SUBMISSION**

Modification of a cleared device

**15. SUBMISSION TYPE**

Traditional 510(k)

**16. DEVICE DESCRIPTION**

The **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging**, is an interventional X-ray system with a floor mounted C-arm as its main configuration. An optional ceiling mounted C-arm is available to provide a bi-plane configuration where required. Additional units include a patient table, X-ray high-voltage generator and a digital radiography system. The C-arms can be configured with designated X-ray detectors and supporting hardware (e.g. X-ray tube and diagnostic X-ray beam limiting device). The **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging** includes αEvolve Imaging, an imaging chain intended for adults, with Artificial Intelligence Denoising (AID) designed to reduce noise in real-time fluoroscopic images and signal enhancement algorithm, Multi Frequency Processing (MFP).

**17. 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.

αEvolve Imaging is an imaging chain intended for adults, with Artificial Intelligence Denoising (AID) designed to reduce noise in real-time fluoroscopic images and signal enhancement algorithm, Multi Frequency Processing (MFP).

**18. SUBSTANTIAL EQUIVALENCE**

The **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging** is substantially equivalent to the Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5, which received premarket clearance under K233107, marketed by Canon Medical Systems. The intended use of the **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging** is the same as that of the predicate device. A comparison of the technological characteristics between the subject and the predicate device is included below.

| | Predicate Device | Subject Device |
|---|---|---|
| Device Name, Model Number | Alphenix, INFX-8000V/B, INFX-8000V/S, V9.5 | Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging |
| 510(k) Number | K233107 | This submission |
| Software to support αEvolve Imaging | Not Available | Available |
| Stylish Design Cover XGSD-120H/B1 (/BU for upgrade) | Not Available | Available |
| Deep Learning Server XIDF-DLS801 for αEvolve Imaging | Not Available | Available |

**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, are met.

**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

**Performance Testing – Bench**

Image Quality Evaluations

Image quality assessments were performed, utilizing phantom and clinical datasets, to evaluate the image quality of the artificial intelligence denoising (AID) algorithm compared to the predicate device, super noise reduction filter (SNRF). The following image quality performance tests were conducted:

1. Change in Image Level, Noise and Structure
   - Raw, AID, and SNRF image sequences of an anthropomorphic chest phantom, acquired at various settings, were compared for noise reduction, change in image level, and preservation of structural similarity index measurement (SSIM) using a student's t-test. The test determined AID to be better at preserving mean image intensity and suggested AID to have improved denoising and image structure preservation.
2. Signal-to-Variance Ratio (SVR) and Signal-to-Noise Ratio (SNR)
   - Anthropomorphic chest phantom images processed with AID and SNRF were compared for SVRs and SNRs measurements using a student's t-test. This test determined the improved ability of AID to preserve image signal while decreasing image noise.
3. Modulation Transfer Function (MTF)
   - The MTF of images denoised by AID and SNRF were visually compared at three key points using a student's t-test. The results of this test showed improved performance for low—to mid-frequencies in all test cases, and the high-frequency region of the MTF curve was found to be similar for AID and SNRF in the majority of cases. The test suggests AID has an improved ability to transfer contrast at various resolutions.
4. Robustness to Detector Defects
   - A comparison of standard images (reference) and images with detector defects, processed with AID, was visually compared for bad pixels and the presence of readout lines that were sufficiently obvious to inform a clinician to call a service technician. The test determined the detector defects were sufficiently obvious to inform the clinician that the detector needed service. Additionally, the image quality outside the area of the detector defect remained visually unaffected, facilitating sufficient image quality to finish the procedure.

5. Normalizes Noise Power Spectrum (NNPS)
    - Flat field fluoroscopic images, denoised using AID and SNRF, were compared for the magnitude and shape of the NNPS. The results of this test found that AID had a smaller noise magnitude in the frequency range of ~0.1 cycles/mm to 1.4 cycles/mm. While AID had a larger noise magnitude than SNRF above 1.4 cycles/mm, both algorithms had very small noise magnitudes at these frequencies and the difference was considered negligible. Additionally, AID had increased noise magnitudes at frequencies below ~0.1 cycles/mm and a different noise texture. This tradeoff may be attributed to these frequencies improved spatial resolution (i.e., MTF), which was evaluated using a reader study.
6. Image Lag Measurement
    - The measured mean image intensity of RAW, AID, and SRNF images was compared to the mean background image intensity using a student's t-test to determine whether there was a significant difference. This test determined that AID performed better in reducing image lag.
7. Contrast-to-Noise Ratio of a Low Contrast Object
    - Fluoroscopic image sequences of the low-contrast phantom were acquired using AID and SNRF processing, and the CNR of each low-contrast element in the phantom was compared using a student's t-test. The results showed AID had a significantly higher CNR than images processed with SNRF for all elements and test cases before and after post-processing with the remainder of the imaging chain. This test supports that AID significantly improves the CNR of low-contrast objects.
8. Contrast-to-Noise Ratio of a High Contrast Object
    - Fluoroscopic image sequences of the anthropomorphic chest phantom were acquired using AID and SNRF processing and the CNR of the guide wire tip and vessels in the phantom was compared using a student's t-test. The results showed AID had a significantly higher vessel and guidewire CNR than images processed with SNRF for all test cases before and after post-processing with the remainder of the imaging chain. This test supports that AID significantly improves the CNR of high-contrast objects.

Additionally, testing with a diverse clinical data set was performed to demonstrate the generalizability of the algorithm. It was concluded that the subject algorithm demonstrated equivalent or improved performance, compared to the predicate device, as demonstrated by the results of the above testing.

**Performance Testing – Clinical Images**

Patient image sequences from the AID and SNRF imaging chains were acquired from Memorial Hermann Hospital (Houston, Texas), Waikato Hospital (Hamilton, New Zealand), and Saiseikai Kumamoto Hospital (Kumamoto, Japan). The patient image sequences were then split into four body mass index (BMI) subgroups for side-by-side comparison and reviewed by United States board-certified interventional cardiologists. This test was considered successful if the Wilcoxon signed rank test found superior performance of the AID imaging chain compared to SNRF. For the overall preference, the test was successful if the Binomial test found that the image sequences denoised by AID were chosen significantly more than 50% of the time. The reader study determined that the mean score of the AID imaging chain images was significantly higher than that of the SNRF imaging chain with regard to sharpness, contrast, confidence, noise, and the absence of image artifacts.

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.

Software Documentation for a Basic Documentation Level, per the FDA guidance document, "Content of Premarket Submissions for Device Software Functions" issued on June 14, 2023, was determined appropriate. This documentation includes justification for the Basic Documentation Level determination as well as testing which demonstrates that the verification and validation requirements have been met.

Cybersecurity documentation followed FDA cybersecurity premarket guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" issued on September 27, 2023.

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

## 21. CONCLUSION

The **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging**, performs in a manner similar to and is intended for the same use as the predicate device, as indicated in the product labeling. Based upon this information, conformance to standards, successful completion of software validation, application of risk management, and design controls, it is concluded that the subject device has demonstrated substantial equivalence to the predicate device and is as safe and effective for its intended use.