March 10, 2026

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

Re: K253584
Trade/Device Name: Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with aEvolve Imaging (FOV Extension)
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: November 17, 2025
Received: March 2, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K258534

Please provide the device trade name(s).

Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging (FOV Extension)

Please provide your Indications for Use below.

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).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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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5. **ESTABLISHMENT REGISTRATION**
   9614698

6. **DATE PREPARED**
   November 17, 2025

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

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, V9.6 with αEvolve Imaging**
Marketed by	**Canon Medical Systems USA, Inc.**
510(k) Number	**K251602**
Clearance Date	**October 10, 2025**
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 (FOV Extension)**, 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). With **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging (FOV Extension)**, the αEvolve Imaging feature now supports 12-inch, 10-inch, and 3-inch fields of view (FOV) for imaging in adult patients. The αEvolve imaging chain incorporates Artificial Intelligence Denoising (AID) for real-time fluoroscopic noise reduction, as well as Multi-Frequency Processing (MFP), a signal enhancement algorithm.

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 (FOV Extension)** is substantially equivalent to the Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging, which received premarket clearance under K251602, marketed by Canon Medical Systems. The intended use of the **Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging (FOV Extension)** 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, V9.6 with αEvolve Imaging	Alphenix, INFX-8000V/B, INFX-8000V/S, V9.6 with αEvolve Imaging (FOV Extension)
510(k) Number	K251602	This submission
FOV of αEvolve Imaging	8-inch, 6-inch (non-binning)	12-inch, 10inch (binning) 8-inch, 6-inch (non-binning) 3-inch (hi-def, non-binning)

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 60601-4-2:201

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:

Binning Mode Bench Test Results

1. Change in Image Level, Noise Magnitude and Signal-to-Noise Ratio (SNR)
   - AID and SNRF image sequences of an anthropomorphic chest phantom were acquired at various settings to evaluate image-level similarity using the Two One-Sided Test (TOST), and to assess noise magnitude and SNR using a one-sided Student's t-test. Results demonstrated that noise and SNR properties of the subject device were equivalent to or better than those of the predicate device in this bench test.
2. Noise Power Spectrum
   - The noise power spectrum (NPS) of fluoroscopic images was evaluated using a PMMA slab phantom, comparing the subject and predicate IP chains. NPS was measured in accordance with IEC 62220-1-1:2015, with success defined as the absence of unexpected distortions (e.g., spikes). Both NPS curves were smooth and free of unexpected distortions. Relative to the predicate IP chain, the subject IP chain exhibited a flatter NPS curve, with lower noise at spatial frequencies below approximately 0.6 cycles/mm and slightly higher noise above that range.
3. Noise Texture via Kurtosis
   - Noise texture was evaluated using kurtosis as a statistical marker with a PMMA slab phantom across four acquisition conditions, utilizing the same dataset used in the Noise Power Spectrum analysis. Success was defined as the subject IP chain's kurtosis being significantly closer to 3 than the predicate ($p < 0.05$) in most test cases. The subject IP chain consistently met this criterion, indicating a more Gaussian-like noise distribution, while the predicate exhibited higher kurtosis, reflecting a heavier-tailed noise distribution.
4. Modulation Transfer Function (MTF)
   - Spatial resolution was assessed by measuring the modulation transfer function (MTF) of fluoroscopic images in accordance with IEC 62220-1-1:2015. Frame-by-frame measurements were averaged to obtain the final normalized MTF curve, with error bars indicating the standard deviation across frames. The test was deemed successful if the MTF curve showed reduced over-enhancement and no unexpected distortions. Both MTF curves were smooth and free of unexpected distortions. The predicate chain exhibited a higher MTF peak, indicating stronger edge enhancement, while the subject IP chain applied more moderate enhancement.

5. Noise Equivalent Quanta
    - Noise Equivalent Quanta (NEQ) was evaluated using previously obtained Noise Power Spectrum (NPS) and Modulation Transfer Function (MTF) data. Success was defined as the subject image processing (IP) chain demonstrating higher NEQ in the low to mid spatial frequency range compared to the predicate IP chain. The results showed that the subject IP chain consistently outperformed the predicate in the 0–0.5 lp/mm range.
6. Low Contrast Detectability
    - Low contrast detectability (LCD) was evaluated for the subject IP chain compared with the predicate using a PMMA slab phantom across four acquisition conditions, utilizing the same dataset used in the Noise Power Spectrum analysis. Custom software measured LCD across various ROI sizes to assess performance at different spatial scales. The test was considered successful if the subject IP chain performed significantly better than the predicate ($p < 0.05$), or if no statistically significant difference was observed in most test cases. Across all conditions, the subject IP chain consistently demonstrated lower percent contrast values than the predicate, indicating superior LCD performance, with improvements statistically significant in all cases ($p < 0.05$).
7. Contrast-to-Noise Ratio of a High Contrast Object
    - This test measured the contrast-to-noise ratio (CNR) in high-contrast regions using a guide wire placed on an anthropomorphic chest phantom containing contrast-enhanced vessels. CNR was measured at the guidewire tip and vessel on a frame-by-frame basis, and results were compared between the subject and predicate IP chains. The test was considered successful if the subject IP chain performed significantly better than the predicate ($p < 0.05$), or if no statistically significant difference was observed in most test cases. Results showed that the subject IP chain significantly outperformed the predicate in all cases ($p < 0.05$), indicating a consistent and statistically significant improvement in CNR for high-contrast objects.

<u>Hi-Def Mode Bench Test Results</u>

1. Change in Image Level, Noise Magnitude and Signal-to-Noise Ratio (SNR)
    - AID and SNRF image sequences of an anthropomorphic chest phantom, at various PMMA thicknesses, were acquired at various settings to evaluate image-level similarity using the Two One-Sided Test (TOST), and to assess noise magnitude and SNR using a one-sided Student's t-test. Results demonstrated that noise and SNR properties of the subject device were better than those of the predicate device in this bench test.

2. Noise Power Spectrum
   - The noise power spectrum (NPS) of fluoroscopic images was evaluated using a PMMA slab phantom, comparing the subject and predicate IP chains. NPS was measured in accordance with IEC 62220-1-1:2015, with success defined as the absence of unexpected distortions (e.g., spikes) and a reduction in noise at high spatial frequencies. Both NPS curves were smooth and free of unexpected distortions. Relative to the predicate IP chain, the subject IP chain exhibited lower noise at spatial frequencies at mid and high frequencies above 2 cycles/mm.
3. Noise Texture via Kurtosis
   - Noise texture was evaluated using kurtosis as a statistical marker with a PMMA slab phantom across four acquisition conditions, utilizing the same dataset used in the Noise Power Spectrum analysis. Success was defined as the subject IP chain's kurtosis being significantly closer to 3 than the predicate ($p < 0.05$) in most test cases. The subject IP chain consistently met this criterion, indicating a more Gaussian-like noise texture and statistically lower kurtosis than the predicate.
4. Modulation Transfer Function (MTF)
   - Spatial resolution was assessed by measuring the modulation transfer function (MTF) of fluoroscopic images in accordance with IEC 62220-1-1:2015. Frame-by-frame measurements were averaged to obtain the final normalized MTF curve, with error bars indicating the standard deviation across frames. The test is considered acceptable if the Noise Equivalent Quanta (NEQ) in *Test 5: Noise Equivalent Quanta* is maintained or improved in the higher spatial frequency range. Both MTF curves were smooth and free of unexpected distortions, and the subject IP chain demonstrated lower spatial resolution than the predicate chain.
5. Noise Equivalent Quanta
   - Noise Equivalent Quanta (NEQ) was evaluated using previously obtained Noise Power Spectrum (NPS) and Modulation Transfer Function (MTF) data. Success was defined as the subject IP chain exhibiting higher NEQ in the mid to high spatial frequency range compared with the predicate IP chain. Results demonstrated that the subject IP chain consistently outperformed the predicate in mid and high frequencies.
6. Low Contrast Detectability
   - Low contrast detectability (LCD) was evaluated for the subject IP chain compared with the predicate using a PMMA slab phantom across four acquisition conditions, utilizing the same dataset used in the Noise Power Spectrum analysis. Custom software measured LCD across various ROI sizes to assess performance at different spatial scales. The test was considered successful if the subject IP chain performed significantly better than the predicate ($p < 0.05$). The results were considered acceptable, as the subject IP chain outperformed the predicate in the majority of ROI sizes (3 out of 4).

7. Contrast-to-Noise Ratio of a High Contrast Object
    - This test measured the contrast-to-noise ratio (CNR) in high-contrast regions using a guide wire placed on an anthropomorphic chest phantom containing contrast-enhanced vessels. CNR was measured at the guidewire tip and vessel on a frame-by-frame basis, and results were compared between the subject and predicate IP chains. The test was considered successful if the subject IP chain performed significantly better than the predicate ($p < 0.05$) in most test cases. Results showed that the subject IP chain significantly outperformed the predicate in all cases, indicating a consistent and statistically significant improvement in CNR for high-contrast objects.

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 (FOV Extension)**, 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.