Canon Medical Systems Corporation
% Mr. Paul Biggins
Senior Director Regulatory Affairs
Canon Medical Systems USA, INC.
2441 Michelle Drive
TUSTIN CA 92780

December 18, 2020

Re: K203551
Trade/Device Name: Alphenix, INFX-8000V/B, INFX-8000V/S V9.1
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB
Dated: December 1, 2020
Received: December 4, 2020

Dear Mr. 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K203551

Device Name

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

Indications for Use *(Describe)*

This device is a digital radiography/fluoroscopy system used in a diagnostic and interventional angiography configuration. The system is indicate 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K203551

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. SUBMITTER'S NAME

Canon Medical Systems Corporation
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4. MANUFACTURING SITE

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Otawara-shi, Tochigi 324-8550, Japan

5. ESTABLISHMENT REGISTRATION

9614698

6. DATE PREPARED

December 1, 2020

7. TRADE NAME(S)

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

8. DEVICE NAME

Interventional Fluoroscopic X-ray System

9. CLASSIFICATION PANEL

Radiology

10. DEVICE CLASSIFICATION

Class II (per 21 CFR 892.1650)

11. PRODUCT CODE / DESCRIPTION

Product Code: OWB - Image-Intensified Fluoroscopic X-ray System

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

Classification Name	**Image-Intensified Fluoroscopic X-ray System**		
Product	**OWB**		
Regulation	**21 CFR 892.1650**		
Regulatory	**Class II**		
Trade	**Alphenix, INFX-8000V/B, V8.0**		
510(K) Number	**K181670**	**Clearance Date**	**July 25, 2018**

14. REASON FOR SUBMISSION

Modification of a cleared device

15. SUBMISSION TYPE

Special 510(k)

16. DEVICE DESCRIPTION

The **Alphenix, INFX-8000V/B, /S V9.1**, 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.

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.

18. SUMMARY OF CHANGE(S)

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

Summary of Software Changes

- **V9.1 Software:** System software changed from V8.0 to V9.1 for improved usability and to support the new tube.
- **Summary of other software changes since K181670**

  V8.0 to V8.3
  - Pulsed fluoroscopy improvement
  - Usability/Operability improvement
  - Service Improvements (non-clinical)

  V8.3 to V9.0
  - Operating System update from Windows 7 to Windows 10
  - AlphaCT IQ improvement
  - 2D IQ Improvement
  - Dose optimization for DSA and spot fluoroscopy
  - Usability/Operability improvement
  - Service Improvements (non-clinical)
  - Cybersecurity improvement

Summary of Hardware Changes

X-ray Tube DSRX-T7634GFS (subject modification)
This x-ray tube replaces the previous DSRX-T7444GDS x-ray tube. The changes to this tube are as follows;

- A change in the instantaneous output at 10% power to 28.8 kW from the previous 22kW.
- A change in the pulsed fluoroscopy maximum mA from 200mA to 320mA
- ABC control is optimized for the new tube
- **C-arm CAS-880A** this was a modification to change the floor sensor back to an earlier version that originally cleared via K081582.

X-ray generator modification

- Increase in pulsed fluoroscopy peak power (kW) for cardiac x-ray tube DRSX-T7444GDS from 17kW to 22kW at duty factor of 10% or less.
- X-ray generator modification to reduce the heat generation in the power circuit.
- Change of the supplemental symbol for the DSRX-T7444GDS from RUB to RXB when used in conjunction with this x-ray generator modification.

Usability/operability improvements (Internal Documentation LTF-181670-001)

- Modified foot switch for INFX-8000V/B (bi-plane configuration)
- Enabled one shot radiography at every acquisition program (DA, DSA, etc.) using modified footswitch.
- Modified table side consoles are 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 and IEC60601-2-28. 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

- ANSI AAMI ES 60601-1:2005/(R) 2012+A1:2012
- IEC 60601-1-2:2014
- IEC 60601-1-3:2008 +A1:2013
- IEC 60601-1-6:2010 +A1:2013
- IEC 60601-2-28:2017
- IEC 60601-2-43:2010 +A1:2017
- IEC 62304:2006 +A1:2015
- IEC 62366:2007 +A1:2014

20. TESTING

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

testing to IEC standards and phantom testing was conducted to verify image metrics related to improvements and changes to the predicate device. Clinical images were deemed not necessary for the aforementioned improvements via design control and risk management activities.

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.

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 V9.1, is substantially equivalent to the INFX-8000V, V8.0, (K181670), marketed by Canon Medical Systems USA. The Alphenix, INFX-8000V/B, INFX-8000V/S V9.1, includes system software change from V8.0 to V9.1, a new cardiac x-ray tube, usability improvements and operability improvements. 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 use of the device.

22. CONCLUSION

The **Alphenix, INFX-8000V/B, INFX-8000V/S V9.1**, 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.