July 25, 2018

Canon Medical Systems Corporation
% Ms. Janine Reyes
Manager, Regulatory Affairs
Canon Medical Systems USA
2441 Michelle Drive
TUSTIN CA 92780

Re: K181670
Trade/Device Name: Alphenix, INFX-8000V/B, V8.0
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB
Dated: June 22, 2018
Received: June 25, 2018

Dear Ms. Reyes:

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); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
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)*

K181670

Device Name

Alphenix, INFX-8000V/B, V8.0

Indications for Use *(Describe)*

This device is a digital radiography/fluoroscopy system used in a diagnostic 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.

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Canon
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, V8.0**

2. **SUBMITTER'S NAME**

Canon Medical Systems Corporation
1385 Shimoishigami
Otawara-Shi, Tochigi-ken, Japan 324-8550

3. **OFFICIAL CORRESPONDENT**

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5. **MANUFACTURING SITE**

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6. **ESTABLISHMENT REGISTRATION**

9614698

7. **DATE PREPARED**

June 22, 2018

8. **TRADE NAME(S)**

Alphenix, INFX-8000V/B, V8.0

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

Infinix, INFX-8000V, V7.0 (K172863)

Product	Marketed by	510(k) Number	Clearance Date
Infinix, INFX-8000V, V7.0	Canon Medical Systems USA	K172863	December 14, 2017

15. REASON FOR SUBMISSION

Modification of a cleared device

16. SUBMISSION TYPE

Traditional 510(k)

17. DEVICE DESCRIPTION

The **Alphenix, INFX-8000V/B, V8.0**, 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. SUMMARY OF CHANGE(S)

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

- **V8.0 Software:** System software changed from V7.0 to V8.0 for improved usability.
- **Tablet Console:** used in combination with the Alphenix, INFX-8000V/B, V8.0, the following functions can be performed in the examination room using the tablet console:
  - Selecting a radiographic program
  - Selecting an auto-positioning No.
  - Selecting a function
  - Performing auxiliary operations on the Angio Workstation
  - Performing playback, pause, and frame feeding of dynamic images

- Switching dynamic image files and map image files

- **New Examination Menu:** enables frequently used functions to be registered into the favorites menu for improved workflow.
- **Programming Restructuring:** AlphaCT encompasses CBCT (Cone Beam CT) programs 3D-DA, LD-3D and LCI.
- **Spot ROI Fluoroscopy for Cardiac:** Spot ROI Fluoroscopy is now available with 8" FPD. Spot ROI (region of interest) Fluoroscopy allows for peripheral region visualization outside of the area of interest. Spot ROI Fluoroscopy for 12” x 12” and 12” x 16” FPD was previously cleared under K152696.
- **Multi-phase CBCT (Cone Beam CT):** Multiphase CBCT allows AlphaCT scans to be performed continuously over multiple phases.
- **Sleep Mode:** To reduce the power consumption of the system, the system automatically enters sleep mode. Note that it is possible to adjust the period of time before the system enters sleep mode.
- **UPS (Uninterruptible Power System) Connection Kit**
- **Specification for System Input Power:** system input power is changed from 400V and 200V to 400V only.
- **Hybrid (aSi/CMOS) FPD (Flat Panel Detector), TFP-1200C, Image Quality Improvement:** Cleared under K170909, hybrid type FPD, TFP-1200C, was modified to improve image quality and includes:
  - Noise reduction for TFP-1200C
  - Pixel area and FOV change of the aSi/CMOS region
- **Space Improvement:** To reduce machine room space requirements, racks were introduced for the chiller, water-cooled heat exchanger and large screen monitor system.
- **HSBP (High Speed BiPlane):** For biplane systems in which images must be acquired simultaneously on the frontal and lateral sides, the HSBP (High Speed Biplane) function can be used in combination to achieve high-rate image acquisition. This function can only be used in combination with cardiac biplane systems with 8" FPD.
- **Fluoroscopy Roadmapping:** DSA workflow improvement enables automatic display of subtracted images after completion of mask generation.

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, 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

- IEC 60601-1:2005 +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

21. 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 in image quality. 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.

Cybersecurity documentation, per the FDA cybersecurity premarket guidance document “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices ” issued on October 2, 2014, 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 **Alphenix, INFX-8000V/B, V8.0**, is substantially equivalent to the INFX-8000V, V7.0, (K172863), marketed by Canon Medical Systems USA. The Alphenix, INFX-8000V/B, V8.0, includes system software change from V7.0 to V8.0, Tablet Console, New Examination Menu, Programing Restructuring, Spot ROI Fluoroscopy for 8” FPD, Multi-phase CBCT, Sleep Mode, UPS Connection Kit, Specification for System Input Power Change, TFP-1200C Image Quality Improvement, Space Improvement, HSBP (High Speed BiPlane) and Fluoroscopy Roadmapping DSA workflow improvement.

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.

23. CONCLUSION

The **Alphenix, INFX-8000V/B, V8.0**, 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 into the Alphenix, INFX-8000V/B, V8.0, 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.