Canon, Inc
℅ Mr. Gregory Woodard
Biomedical Engineer
Ken Block Consulting
800 East Campbell Road, Suite 202
RICHARDSON TX 75081

April 15, 2020.

Re: K200887
Trade/Device Name: AS-10
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, MQB, JAA
Dated: March 27, 2020
Received: April 2, 2020

Dear Mr. Woodard:

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)*

K200887

Device Name
AS-10

Indications for Use *(Describe)*

The AS-10 is indicated for use in generating fluoroscopic and radiographic images of human anatomy for angiography, diagnostic, and interventional procedures. The device is intended to replace spot-film devices. The device is also intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Canon

5. 510(k) SUMMARY

Submitter: Canon, Inc.
30-2 Shimomaruko, 3-chrome
Ohta-ku, Tokyo 146-8501 Japan

Contact Person: Mr. Akira Hirai
General Manager
TEL: 81-3-3758-2111
FAX: 81-44-739-6695
hirai.akira@mail.canon

Date Prepared: April 1, 2020

Submission Type: Special 510(k) Submission

Trade Name: AS-10

Common Name: Solid State X-Ray Imager (Flat Panel/Digital Imager)

Classification Name: Image-intensified Fluoroscopic X-ray System

Classification: Primary: 892.1650 (Image-intensified fluoroscopic x-ray system)
Subsequent: 892.1680 (Stationary X-ray System)

Predicate Device: Canon AS-10 / CXDI-401RF
510k Number: K171194
Product Codes: OWB, MQB, JAA

Device Description: The *AS-10* is a solid state x-ray imager. It intercepts x-ray photons and the scintillator of the *AS-10* emits visible spectrum photons that illuminate an array of photo-detectors that create electrical signals. After the electrical signals are generated, it is converted to digital value.

The subject of this Special 510(k) submission is a change to the *AS-10* to make the PowerBox (PB-09), Power Supply Cable, and Optical Cable optional components. This change will allow for the use of any power source and non-Canon cables, given they meet the provided specifications. In addition, changes have been made to the firmware in the *AS-10* detector unit and PowerBox to implement bug fixes and functional improvements. Together, these changes make up the *AS-10*.

Indication for Use: The Indication for Use statement is identical to the predicate device. The intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).

The *AS-10* is indicated for use in generating fluoroscopic and radiographic images of human anatomy for angiography, diagnostic, and interventional procedures. The device is intended to replace spot-film devices. The device is also intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.

Summary of Technological Characteristics:

Comparisons with the predicate devices show the characteristics of the proposed modifications (change to make the PowerBox, Power Supply Cable, and Optical Cable optional accessories) to the *AS-10* to be substantially equivalent to the predicate device.

	Proposed Device	**Predicate Device**	
Trade Name	AS-10	AS-10 / CXDI-401RF	
510(k) Submitter [Number]	Canon, Inc. [TBD]	Canon, Inc. [K171194]	IDENTICAL
Indication for Use	The AS-10 is indicated for use in generating fluoroscopic and radiographic images of human anatomy for angiography, diagnostic, and interventional procedures. The device is intended to replace spot-film devices. The device is also intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.	The AS-10 / CXDI-401RF is indicated for use in generating fluoroscopic and radiographic images of human anatomy for angiography, diagnostic, and interventional procedures. The device is intended to replace spot-film devices. The device is also intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.	IDENTICAL
Application	Fluoroscopy and Spot Radiology	Fluoroscopy and Spot Radiology	IDENTICAL
Technology	Flat panel detector: Scintillator and a-Si	Flat panel detector: Scintillator and a-Si	IDENTICAL
Scintillator	CsI(Tl)	CsI(Tl)	IDENTICAL
Pixel Pitch	160 x 160 µm	160 x 160 µm	IDENTICAL
Pixels	2,688 x 2,688 (≈ 7.2 million)	2,688 x 2,688 (≈ 7.2 million)	IDENTICAL
Image Size	430 x 430 mm	430 x 430 mm	IDENTICAL
Overall Dimensions	469 x 468 x 58 mm	469 x 468 x 58 mm	IDENTICAL
Weight	13 kg	13 kg	IDENTICAL
Acquisition Mode (Binning mode)	Up to 15 fps (1x1) Up to 30 fps (2x2) Up to 30 fps (3x3)	Up to 15 fps (1x1) Up to 30 fps (2x2) Up to 30 fps (3x3)	IDENTICAL
A/D Conversion	16-bit	16-bit	IDENTICAL
Required Components	Detector Unit	Detector Unit Power Supply Cable Optical Cable PowerBox	MODIFIED
Optional Components	Power Supply Cable Optical Cable PowerBox	N/A	MODIFIED
Rated Power Supply Input (Detector Unit)	Ch1: 22V DC (17.0V – 23.1V) 1.1A (Max 1.5A) Ch2: 15V DC (12.0V – 15.3V) 0.6A (Max 1.0A)	N/A	MODIFIED
Rated Power Supply Input (PowerBox)	100 – 240V AC 50/60 Hz 0.9A – 0.3A	100 – 240V AC 50/60 Hz 0.9A – 0.3A	IDENTICAL
Firmware Version (PowerBox)	01.00.00.00	00.02.00.0c	MODIFIED
Firmware Version (Detector Unit)	01.00.00.00	00.02.00.0c	MODIFIED

	The User's and Installation Manuals provide detailed instructions and information for safe and effective use of the device and users are expected to adhere to the instructions and other information. The User's Manual explains how to use the detector and other equipment. Connected medical equipment, such as X-ray generators, must comply with IEC 60601-1. Before using the product, be sure to read the manual thoroughly in order to utilize it more effectively.
Performance:	The fundamental scientific technology of the *AS-10* has not been modified. The detector unit of the AS-10 has not been modified, and the change is to allow the use of commercial components in place of the PowerBox, Optical Cable, and Power Supply Cable. Evaluation of the changes to the *AS-10* confirmed that the changes did not impact *AS-10* conformance with the U.S. Performance Standard for radiographic equipment and with relevant voluntary safety standards for Electrical safety and Electromagnetic Compatibility testing, specifically IEC standards 60601-1, 60601-1-2, 60601-1-3, 60601-1-6, 62366, 60601-2-54, 60825-1, 62220-1, and 62304. These verification/validation activities successfully demonstrated that the device continues to meet the standards for the areas impacted by the device modifications to the predicate device and raises no new questions regarding either safety or effectiveness when compared to the predicate device. Therefore, the verification/validation conducted supports a determination of substantial equivalence for the *AS-10* device.
Conclusion:	*Canon, Inc.* considers the *AS-10* to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.