DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 24, 2017

Canon, Inc. – Medical Equipment Group
% Diane Rutherford
Submission Manager
Ken Block Consulting
1201 Richardson Drive, Suite 160
Richardson, Texas 75080

Re: K171194
Trade/Device Name: AS-10, CXDI-401RF
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, MQB
Dated: April 24, 2017
Received: April 24, 2017

Dear Diane Rutherford:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For

Robert A. 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171194

Device Name
AS-10
CXDI-401RF

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) SUMMARY

Submitter:	Canon, Inc. – Medical Equipment Group 9-1, Imaikami-cho, Nakahara-ku Kawasaki, Kanagawa 211-8501, Japan	
Contact Person:	Canon, Inc. – Medical Equipment Group Mr. Shinji Mori Manager 9-1, Imaikami-cho, Nakahara-ku Kawasaki, Kanagawa 211-8501, Japan TEL: 81-3-3758-2111 FAX: 81-44-739-6493 mori.shinji@canon.co.jp	
Date Prepared:	April 18, 2017	
Proposed Device	Manufacturer:	Canon, Inc. – Medical Equipment Group
	Trade Name:	AS-10 CXDI-401RF
	Common Name:	Solid State X-Ray Imager (Flat Panel/Digital Imager)
	Classification Name:	Interventional Fluoroscopic X-ray System
	Primary Product Code /	OWB
	Regulatory Standard:	892.1650, Image-intensified fluoroscopic x-ray system
	Subsequent Product Codes:	JAA, MQB
Predicate Devices:	Clearance:	K092439 dated November 30, 2009
	Manufacturer:	Virtual Imaging, A Canon USA Company
	Trade Name:	Model CXDI-50RF
	Common Name:	Fluoroscopic Digital X-Ray Receptor Panel
	Classification Name:	Image-Intensified Fluoroscopic X-Ray System
	Product Code(s) /	OWB, JAA, IZI [SE Letter correction July 30, 2012]
	Regulatory Standard(s):	892.1650, Image-intensified fluoroscopic x-ray system 892.1600, Angiographic x-ray system [Originally cleared under MQB, 892.1680]
	Clearance:	K162909 dated January 27, 2017
	Manufacturer:	Canon, Inc. – Medical Equipment Group
	Trade Name:	Model CSX-30
	Common Name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
	Classification Name:	Stationary X-ray system
	Primary Product Code	MQB
	Regulatory Standard:	892.1680, Stationary X-ray System
	Subsequent Product Code	JAA
	Regulatory Standard:	892.1650, Image-intensified fluoroscopic x-ray system
Device Description:	The AS-10 / CXDI-401RF is a solid state x-ray imager. It intercepts x-ray photons and the scintillator of the AS-10 / CXDI-401RF 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.	

Canon

Indications for Use: 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.

Summary of Technological Characteristics: Comparison with the predicate devices shows the technological characteristics of the AS-10 / CXDI-401RF is substantially equivalent to the predicate devices. The flat panel detector units are functionally identical.

The AS-10 / CXDI-401RF is a successor model of the CXDI-50RF; however, the AS-10 / CXDI-401RF is for integration only like the CSX-30. The differences between the AS-10 / CXDI-401RF and the predicates CXDI-50RF and CSX-30 are primarily overall dimensions, increased pixels, and increased image size.

The differences between the AS-10 / CXDI-401RF and the predicates are primarily increased size. Increased size results in larger dimensions, larger image area, more pixels, and weight differences over the predicate. An additional binning mode has been added to the AS-10 / CXDI-401RF in an effort to improve the marketability. The proposed indications for use statement differs slightly in wording from the predicates, but does not impact the intended use. The proposed and both predicate devices are indicated for fluoroscopic and radiographic use.

In the table below, the predicates are identified as a) CXDI-50RF or b) CSX-30. If no letter precedes the predicate information, the information applies to both predicates.

	New Device: AS-10 / CXDI-401RF K171194	**Predicate Devices: a) CXDI-50RF K092439 b) CSX-30 K162909**	
Application	Fluoroscopy and Spot Radiology	Fluoroscopy and Spot Radiology	Identical
Technology	Flat panel detector: Scintillator and a-Si	Flat panel detector: a) 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)	a) 2,208 x 2,688 (≈ 5.9 million) b) 2,496 x 1,856 (≈ 4.6 million)	Modified
Image Size	430 x 430 mm	a) 350 x 430 mm b) 399 x 297 mm	Modified
Overall Dimensions	469 x 468 x 58 mm	a) 493 x 503 x 26 mm b) 470 x 363 x 82.5 mm (Except tubes protrusions)	Modified
Weight	13 kg	a) 5.7 kg b) 19.0 kg	Modified
Acquisition Mode (Binning mode)	Up to 15 fps (1x1) Up to 30 fps (2x2) Up to 30 fps (3x3)	a) Up to 15 fps (1x1) b) Up to 30 fps (2x2)	Identical Identical Modified
DQE @ 1 µGy in 0 lp/mm, RQA5	0.75	a) 0.6 b) 0.79	Modified Modified
Spatial Resolution [MTF@2cycle/mm, RQA5]	0.28	a) 0.3 b) 0.22	Modified Modified
A/D Conversion	16-bit	a) 14-bit b) 16-bit	Modified Identical

Summary of Non-Clinical /Test Data:	Tests were performed on the device which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate devices. Tests included verification/validation testing to internal functional specifications (including software) and non-clinical image comparisons involving flat panel display static and dynamic images taken with the new device and the predicate device CXDI-50RF. Documentation was provided demonstrating compliance of the AS-10 / CXDI-401RF to all FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation plus traceability of verification/validation tests to software requirements and software risk hazards. Documentation was provided demonstrating that the AS-10 / CXDI-401RF complies with the FDA requirements stated in Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices. The evaluations of the AS-10 / CXDI-401RF compared to the CXDI-50RF, show the AS-10 / CXDI-401RF to be equivalent to the CXDI-50RF. Testing confirmed that the AS-10 / CXDI-401RF complies 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, 60601-2-54, 62304, and 62366 as well as ANSI/AAMI ES60601-1. Testing also confirmed compliance to relevant voluntary safety standard IEC 60825-1. Together, these verification/validation activities successfully demonstrated that the AS-10 / CXDI-401RF correctly performs as designed, has been validated for its intended use, and raises no new questions regarding either safety or effectiveness when compared to the predicate devices. Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the AS-10 / CXDI-401RF device.
Integration:	The AS-10 / CXDI-401RF is a hardware only FPD for integration into dynamic and static imaging systems. The AS-10 / CXDI-401RF connects to the image capture unit (compliant with IEC 60601-1 or IEC 60950-1) through a wired connection and does not connect directly to an x-ray generator. The Installation Manual provides detailed instructions and information for safe and effective system integration including: system configuration; electrical, mechanical, and cooling requirements; installation conditions; interfaces (image, command and service, and power input). Integrators are expected to adhere to the instructions and other information in the published Installation Manual.
Conclusion:	*Canon, Inc. – Medical Equipment Group* considers the AS-10 / CXDI-401RF to be substantially equivalent to the predicate devices listed above. This conclusion is based on the same intended use and similar principles of operation, functional design, and established medical use for the flat panel detector.