DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 27, 2017

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

Re: K162909
Trade/Device Name: CSX-30 Flat Panel Detector
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB, JAA
Dated: December 27, 2016
Received: December 28, 2016

Dear Ms. 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 yours,

For

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162909

Device Name
CSX-30 Flat Panel Detector

Indications for Use *(Describe)*
The flat panel detector CSX-30 is designed to provide fluoroscopic and spot radiographic images of human anatomy during diagnostic, surgical and interventional procedures. Examples of clinical application may include angiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical-care and emergency room procedures or other imaging applications at the physician's discretion. 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)*

5. 510(k) SUMMARY

Submitter:	Canon, Inc. – Medical Equipment Group 9-1, Imaikami-cho, Nakahara-ku Kawasaki, Kanagawa 211-8501, Japan	
Contact Person:	Mr. Shinji Mori Manager TEL: 81-3-3758-2111 FAX: 81-44-739-6493 shinji.mori@canon.co.jp	
Date Prepared:	September 27, 2016	
Proposed Device	Manufacturer: Trade Name: Common Name: Classification Name: Product Code / Regulatory Standard:	Canon CSX-30 Flat Panel Detector Solid State X-ray Imager Stationary X-ray system MQB, JAA 892.1680 Stationary X-ray System
Predicate Device:	Clearance: Manufacturer: Trade Name: Common Name: Classification Name: Product Code / Regulatory Standard:	K111824 dated April 23, 2012 Canon CSX-10 Flat Panel Detector Solid State X-ray Imager Stationary X-ray system MQB 892.1680 Stationary X-ray System
Device Description:	The CSX-30 is a digital radiography flat panel detector that can take fluoroscopic and spot radiographic images of any part of the body. It directly converts the X-ray images captured by the sensor into high-resolution digital images. The instrument is a component of an x-ray system and as such cannot be used outside of such a system. This unit converts the X-rays into digital signals. Not intended for mammography applications.	
Indications for Use:	The flat panel detector CSX-30 is designed to provide fluoroscopic and spot radiographic images of human anatomy during diagnostic, surgical and interventional procedures. Examples of clinical application may include angiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical-care and emergency room procedures or other imaging applications at the physician's discretion. 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 Intended Use of the CSX-30 is the same as for the predicate device, CSX-10.	
Summary of Technological Characteristics:	Comparison with the predicate shows the technological characteristics of the CSX-30 are substantially equivalent to the predicate device. The flat panel detector units are functionally identical. The CSX-30 is the next model in the CSX family of detectors. The differences between the CSX-30 and the predicate CSX-10 are primarily increased size and increased performance. Increased size results in larger dimensions, larger image	

area, more pixels, and increased weight over the predicate. Performance has been increased resulting in increased DQE, dynamic range, and frame rates. These modifications have been incorporated into the CSX-30 in an effort to improve the product performance.

	New Device: CSX-30 K162909	**Predicate Device: CSX-10 K111824**	
Application	Fluoroscopy and Spot Radiology	Fluoroscopy and Spot Radiology	Identical
Technology	Flat panel detector: Scintillator and CSX sensing unit	Flat panel detector: Scintillator and CSX sensing unit	Identical
Scintillator	CsI(Tl) [Cesium Iodide doped with Thallium]	CsI(Tl) [Cesium Iodide doped with Thallium]	Identical
Pixel Pitch	160 x 160 µm	160 x 160 µm	Identical
Pixels	2,496 x 1,856 (approx 4.6 million)	1,792 x 1,632 (approx 2.9 million)	Modified
Image Size	399 x 297 mm	287 x 261 mm	Modified
Overall Dimensions	470 x 363 x 82.5 mm (Except flexible tubes and minor protrusions)	360 x 346 x 65.5 mm	Modified
Weight	19.0 kg	6.7 kg	Modified
Acquisition Mode (Binning mode)	Up to 60 fps (1x1) Up to 230 fps (2x2) Up to 300 fps (4x4)	Up to 30 fps (1x1) Up to 100 fps (2x2) Up to 200 fps (4x4)	Modified Modified Modified
A/D Conversion	16-bit	14-bit	Modified

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 device.

Tests included verification/validation testing to internal functional specifications (including software) and non-clinical image comparisons involving flat panel display images taken with the new device and the predicate devices. Documentation was provided demonstrating compliance of the CSX-30 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 CSX-30 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 CSX-30 compared to the CSX-10, show the CSX-30 to be equivalent to the CSX-10.

Testing confirmed that the CSX-30 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, 60601-1-9, 60601-2-32, and 60601-2-54. Testing also confirmed compliance to relevant voluntary safety standards IEC 60825-2, IEC 60825-1, and IEC 62220-1-3.

Together, these verification/validation activities successfully demonstrated that the CSX-30 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 CSX-30 device.

Integration:	The CSX-30 is a hardware only FPD for integration into x-ray systems. The CSX-30 connects to an x-ray imager control PC and does not connect directly to an x-ray generator. The Instruction 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 *CSX-30* to be substantially equivalent to the predicate device 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.