DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 28, 2016

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

Re: K153312
Trade/Device Name: Scatter Correction for CXDI Series
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 25, 2016
Received: May 26, 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)*

Device Name
Scatter Correction for CXDI Series

Indications for Use *(Describe)*
As a part of the CXDI series radiography system, the CXDI Control Software when used with a compatible CXDI detector is intended to provide digital image capture, processing, and display for conventional film/screen radiographic examinations. This device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures including specialist areas like intensive care, trauma, and pediatric work. This device is not intended for fluoroscopic, angiographic, or 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 30-2 Shimomaruko, 3-chrome Ohta-ku, Tokyo 146-8501 Japan
Contact Person:	Mr. Shinji Mori Manager TEL: 81-3-3758-2111; FAX: 81-3-5482-3960 mori.shinji@canon.co.jp
Date Prepared:	*November 6, 2015 [revised May 23, 2016]*
Trade Name:	Scatter Correction for CXDI Series
Common Name:	Control Software for Flat Panel Digital Imager
Classification Name:	MQB (Solid State X-Ray Imager, Flat Panel/Digital Imager) 892.1680 (Stationary X-Ray System)

Predicate Devices:

Predicate 1: MQB — Canon DIGITAL RADIOGRAPHY CXDI Series Detectors

510(k) #	Models
K102012	CXDI-70C Wireless
K103591	CXDI-401C, CXDI-401G, CXDI-401C Compact, CXDI-401G Compact
K111682	CXDI-501C, CXDI-501G
K112309	CXDI-80C Wireless, CXDI-80G Wireless
K131106	CXDI-701C Wireless, CXDI-701G Wireless, CXDI-801C Wireless, CXDI-801G Wireless
K133693	CXDI-401C Wireless

Predicate 2: MQB / LLZ K140771 Philips Elva Workspot with Skyflow

Device Description: The subject of this submission is a change to the CXDI Control Software to incorporate a scatter correction algorithm. By incorporating the scatter correction algorithm into the CXDI Control Software, the image contrast is enhanced and the images produced have similar detail contrast as images acquired with an anti-scatter grid.

5. 510(k) SUMMARY (continued)

Statement of Intended Use: [Indications for Use Statement]	As a part of the CXDI series radiography system, the CXDI Control Software when used with a compatible CXDI detector is intended to provide digital image capture, processing, and display for conventional film/screen radiographic examinations. This device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures including specialist areas like intensive care, trauma, and pediatric work. This device is not intended for fluoroscopic, angiographic, or mammography applications.
Summary of Technological Characteristics:	Comparisons with the predicate device(s) show the characteristics of the proposed *Scatter Correction for CXDI Series* to be substantially equivalent to the predicate device(s). The Canon CXDI Control NE software with scatter correction can only be used with compatible Canon CXDI detectors: CXDI-70C Wireless, CXDI-80C Wireless, CXDI-80G Wireless, CXDI-401C, CXDI-401C Wireless CXDI-401G, CXDI-401C Compact, CXDI-401G Compact, CXDI-501C, CXDI-501G, CXDI-701C Wireless, CXDI-701G Wireless, CXDI-801C Wireless, CXDI-801G Wireless.
Summary of Non-Clinical / Test Data:	Tests were performed on the proposed CXDI Control Software which demonstrates that the device is safe and effective, performs comparably to the predicate device(s), and is substantially equivalent to the predicate device(s). Tests included verification/validation testing to internal software specifications and image comparisons involving flat panel display images taken without a grid. Additional evaluations were conducted with clinical images to demonstrate and evaluate the performance of the software feature. Documentation was provided demonstrating compliance of the CXDI Control Software 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. Together, these verification/validation activities successfully demonstrated that the *Scatter Correction for CXDI Series* 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 device(s). Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the *Scatter Correction for CXDI Series*. As reported in prior submissions to FDA, the compatible detectors comply 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, and 60601-2-32. The wireless detectors also comply with the FCC test standard for SAR, specifically 47CFR 2.1093 and for EMI test regulations FCC Part 15 Subpart B:2012 Class A and ICES-003 Issue 5:2012 Class A.
Conclusion:	*Canon, Inc. – Medical Equipment Group* considers the *Scatter Correction for CXDI Series* 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.