Canon, Inc.
% Ms. Katie Reneson
Regulatory Specialist
Ken Block Consulting
800 East Campbell Road, Suite 202
RICHARDSON TX 75081

March 13, 2019

Re: K190368
Trade/Device Name: Enhanced Feature Software Pack for CXDI Series
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: February 14, 2019
Received: February 15, 2019

Dear Ms. Reneson:

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/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,

Michael D. O'Hara For

Thalia Mills, 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)*

K190368

Device Name

Enhanced Feature Software Pack 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Canon

5. Special 510(k) SUMMARY

Submitter: Canon, Inc.
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Date Prepared: February 14, 2019

Submission Type: Special 510(k) Submission

Trade Name: Enhanced Feature Software Pack for CXDI Series

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

Regulatory Number: 21 CFR 892.1680

Classification Name: Stationary X-ray system

Product Code: MQB

Primary Predicate #1: MQB K153312 Scatter Correction for CXDI Series

Predicate #2: MQB Canon DIGITAL RADIOGRAPHY CXDI Series Detectors

510(k) #	Models
K170332	CXDI-710C Wireless
K171270	CXDI-410C Wireless

Device Description: The subject of this Special 510(k) submission is a change to the CXDI Control Software to incorporate the ability to capture an automatically stitched long length image in a single exposure. The addition of the One Shot Long Length to the cleared Scatter Correction of CXDI Series is the subject of this Special 510(k) Submission. The One Shot Long Length stitches long length images into a single image which is accomplished by using multiple detectors, a single exposure, and the automatic stitching software. The One Shot Long Length software feature along with the Scatter Correction cleared under K153312 make up the Enhanced Feature Software Pack for CXDI Series. The Scatter Correction clearance and compatible detectors are not impacted by this submission. This submission adds the One Shot Long Length feature to limited compatible FPDs. The One Shot Long Length feature included in the Enhanced Feature Software Pack for CXDI Series also includes features for manual stitching to allow for users to manually adjust and fine-tune the stitch positions after the automatic stitch operation. By incorporating the One Shot Long Length imaging into the CXDI Control Software, images up to 120cm in length can be acquired in one exposure. The firmware within the flat panel detectors did not require updating. The flat panel detectors that have been previously cleared by FDA and are compatible with the Enhanced Feature Software Pack for CXDI Series have not been physically modified and performance have not changed.

Indications for Use Statement

The intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).

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 devices show the characteristics of the proposed addition of the One Shot Long Length feature to the Enhanced Feature Software Pack for CXDI Series to be substantially equivalent to the predicate device(s). The One Shot Long Length feature of the Enhanced Feature Software Pack for CXDI Series can only be used with compatible Canon CXDI detectors CXDI-710C Wireless, CXDI-410C Wireless.

Trade Name	**Proposed Device** Enhanced Feature Software Pack for CXDI Series	**Predicate** Control Software V2.14 Scatter Correction	
510(k) Submitter [Number]	Canon, Inc. [K190368]	Canon, Inc. [K153312]	IDENTICAL
Indication for Use	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.	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.	IDENTICAL
Scatter Correction	An image can be created (with high contrasts) by using software algorithm, in clinical field, without a grid	An image can be created (with high contrasts) by using software algorithm, in clinical field, without a grid	IDENTICAL
One Shot Long Length Imaging	One exposure to obtain images across multiple detectors, automatically stitched together with ability to make manual adjustments after the automatic stitching.	N/A	MODIFIED
Software /Version	CXDI Control Software V2.17	CXDI Control Software V2.14 (highest version cleared previously)	MODIFIED

	Proposed Device Canon DIGITAL RADIOGRAPHY CXDI Series Detectors containing Enhanced Feature Software Pack for CXDI Series	**Predicate Device** Canon DIGITAL RADIOGRAPHY CXDI Series Detectors	
Trade Name			
510(k) Submitter [Number]	Canon, Inc. [K190368]	Canon, Inc. [K170332, K171270]	IDENTICAL
Indication for Use	The DIGITAL RADIOGRAPHY CXDI Series Detectors provides digital image capture for conventional film/screen radiographic examinations. This device is intended to capture for display radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.	The DIGITAL RADIOGRAPHY CXDI Series Detectors provides digital image capture for conventional film/screen radiographic examinations. This device is intended to capture for display radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.	IDENTICAL
Scatter Correction	An image can be created (with high contrasts) by using software algorithm, in clinical field, without a grid	An image can be created (with high contrasts) by using software algorithm, in clinical field, without a grid	IDENTICAL
One Shot Long Length Imaging	One exposure to obtain images across multiple detectors, automatically stitched together with ability to make manual adjustments after the automatic stitching.	N/A	MODIFIED
Firmware /Version	04-02-0c-00	04-02-0b-00	MODIFIED

Performance: The hardware within the Canon Digital Radiography CXDI Series Detectors has not been modified, the detectors have the same performance, biocompatibility, effectiveness, and safety and is substantially equivalent to the predicate device. The risks and hazardous impacts of the device modification were analyzed by FMEA methodology. The specific risk control and protective measures to mitigate the risks from the modification were reviewed and implemented as part of product design. The overall assessment concluded that all identified risks and hazardous conditions were successfully mitigated and accepted.

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. considers the Enhanced Feature Software Pack 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.