SHIMADZU CORPORATION
% Mr. Jeffrey Seiler
Manager, National Service Business
Shimadzu Medical Systems
20101 South Vermont Avenue
TORRANCE CA 90502

Re: K173517
Trade/Device Name: RADspeed fit
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: February 19, 2018
Received: February 21, 2018

Dear Mr. Seiler:

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.

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.

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,

Robert Sauer 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173517

Device Name
RADspeed fit

Indications for Use *(Describe)*
The RADspeed fit is intended to generate digital or conventional radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts of human anatomies in all routine radiography examinations. The RADspeed fit enables radiographic exposure of the whole body of all ages including
pediatric patients. Exposures may be taken with the patient sitting, standing, or lying in the prone or supine position. The RADspeed fit uses portable or integrated flat panel detectors to generate diagnostic images by converting x-rays into electronic signals. The device is also designed to be used with conventional film/screen or computed radiography (CR) cassettes. The device is not intended for mammographic applications or tomographic techniques. The indications for use remain the same as those for the predicate, except for the removal of tomographic technique.
WARNING: United States Federal Law restricts this device to sale by or on the order of a physician.

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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510(k) Summary

The following information is submitted in accordance with the requirements of 21 CFR§807.92.

1) Date of Submission

October 30th, 2017

2) Submitter

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5) Device

Name of Device	: RADspeed fit
Common Name	: General Radiography System
Classification Name	: Stationary x-ray system (21 CFR§892.1680)
Classification Panel	: Radiology
Regulatory Class	: Class II
Product Code	: KPR

6) Predicate Device

Primary	K152244	KPR	RADspeed Pro	SHIMADZU CORPORATON
Secondary	K170332	MQB	Digital Radiography CXDI-710C Wireless Digital Radiography CXDI-810C Wireless	Canon, Inc.

7) Purpose of Submission

The purpose of this submission is to notify FDA of our intent to introduce a modified device of legally marketed devices, K152244 RADspeed Pro manufactured by SHIMADZU CORPORATON. And as the Digital Radiography system, the legally marketed device, K170332 Digital Radiography CXDI-710C Wireless / Digital Radiography CXDI-810C Wireless by Canon, inc. is configured.

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8) Device Description

The RADspeed fit is an X-ray radiography system that is mainly used for the radiography of various regions of the patient's body in a standing or recumbent position. The RADspeed fit can be used in a wide range of applications from general radiography using X-ray film or Computed Radiography (CR) cassettes, to digital radiography. The RADspeed fit consists of an X-ray high voltage generator, X-ray tube unit, X-ray tube support and collimator. The system can be configured with radiographic table, radiographic stand and digital radiography system as well. The X-ray generator of RADspeed fit has the capability to communicate with the digital radiography system to synchronize exposure timing, receive a code to select an anatomical program and to send X-ray technique factors and dose information after exposure.

9) Intended Use

The RADspeed fit is a stationary X-ray system for taking general radiographic images of the whole body. The device is intended to be used in hospitals, clinics, imaging centers, and/or other healthcare facilities by qualified/trained professionals.

10) Indications for Use

The RADspeed fit is intended to generate digital or conventional radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts of human anatomies in all routine radiography examinations. The RADspeed fit enables radiographic exposure of the whole body of all ages including pediatric patients. Exposures may be taken with the patient sitting, standing, or lying in the prone or supine position. The RADspeed fit uses portable or integrated flat panel detectors to generate diagnostic images by converting x-rays into electronic signals. The device is also designed to be used with conventional film/screen or computed radiography (CR) cassettes. The device is not intended for mammographic applications or tomographic techniques. The indications for use remain the same as those for the predicate, except for the removal of tomographic technique.

WARNING: United States Federal Law restricts this device to sale by or on the order of a physician.

11) Comparison of Technological Characteristics with the predicate devices

At a high level, new device and its predicate device are based on the following same technological elements:

- Energy emission to the patient – X-ray
- Power requirement, Environmental requirement
- Mechanism to generate X-ray
- Mechanism to acquire, process and store image data
- Use of the hardware components
- Use of software processing

The modifications to its predicate device K152244 are as follows,

- Removed "Fluoroscopy" function
- Removed "Long View Radiography" function
- Removed "Energy subtraction radiography" function

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- Removed “Tomography function”
- Removed “Tomosynthesis radiography” function
- Removed “Side Station RAD” from the configuration
- As the Digital Radiography system, the legally marketed device, K170332 Digital Radiography CXDI-710C Wireless / Digital Radiography CXDI-810C Wireless by Canon, inc. is configured.
- Added Calculated Dose-Area Product Display Function
- Added FPD Rotation Tray

Since all removed functions mentioned above are for the optional and additional applications of the predicate device, they do not affect safety and essential effectiveness even though they do not exist. And since the Digital Radiography system is completely the same as the predicate device K170332 Digital Radiography CXDI-710C Wireless / Digital Radiography CXDI-810C Wireless by Canon, Inc, there is no difference in image quality performance. The Calculated Dose-Area Product Display Function (added above) is a new feature to indicate calculated dose-area product values as reference purpose only. FPD rotation tray is also an optional item for the user to change the orientation of FPD without detaching from the tray. These added functions and features do not affect safety or overall system effectiveness.

Comparison charts of items which are relevant to image quality are described as follows, especially X-ray High Voltage Generator and Digital Radiography system. As for X-ray High Voltage Generator; Technology, design and specification of the X-ray high voltage generator of new device are substantially equivalent to the one of primary predicate device, except Nominal electric power, Tube current and mAs of new device. It does not affect safety and effectiveness. As for Digital Radiography system, Technology, design and specification of digital radiography system of new device are exactly the same as those of secondary predicate device.

- X-ray High Voltage Generator

Specification		New Device RADspeed fit	Predicate Device RADspeed Pro < K152244>
Radiography technique		Same as predicate	General radiography
		Same as predicate	Bucky radiography
		Not Available	Tomosynthesis / Tomography
		Same as predicate	Digital radiography
Nominal electric power		32kW/56kW	80 kW / 65 kW / 50 kW
Radiography setting	Tube voltage	Same as predicate	40 to 150 kV
	Tube current	10 to 500 mA (32kW) 10 to 630 mA(56kW)	10 to 1000 mA (80kW) 10 to 800 mA (65kW) 10 to 630 mA (50kW)
	mAs	0.5 to 500mAs	0.5 to 800 mAs
	Exposure time	Same as predicate	0.001 to 10 sec

- Digital Radiography system

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Specification	New Device RADspeed fit	Secondary Predicate Device Digital Radiography CXDI-710C Wireless Digital Radiography CXDI-810C Wireless < K170332>
Application	Same as predicate	General Radiography
Scintillator type	Same as predicate	CsI(Tl) [Cesium Iodide doped with Thallium]
Pixel Pitch	Same as predicate	125 μm
Pixels	Same as predicate	710C: 2,800 x 3,408 (≈ 9.5 mil) 810C: 2,800 x 2,192 (≈ 6.1 mil)
External Dimensions	Same as predicate	710C: 384 x 460 x 15.7 mm 810C: 307.5 x 384 x 15.7 mm
Weight	Same as predicate	710C: 2.3 kg 810C: 1.8 kg
Spatial Resolution	Same as predicate	35% [MTF@2lp/mm]
Control SW	Same as predicate	CXDI Control Software
Device FW	Same as predicate	PCA‐FE‐710
Wireless Functions	Same as predicate	Communication between Detector and: Multi Box Control PC

12) Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Electromagnetic compatibility

Both new device and primary predicate device are in conformity with IEC60601-1-2. The difference is edition of the standard. Difference of edition of the standard does not affect safety and effectiveness.

Materials and Bio-compatibility testing

All materials and components of new device are in conformity with IEC10993-1. All materials and components of new device are in clinical use by other commercial products. Difference between new device and primary predicate device does not affect safety and effectiveness.

Sterility

Both new device and primary predicate device are not sterilized.

Electrical, Mechanical, Chemical and Thermal safety

As to these safeties, new device and primary predicate device are substantially equivalent by their conformed standards.

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Software Verification and Validation Testing

Digital radiography system is exactly the same as the predicate (K170332). In order to adapt to the interface of the components and Digital radiography system, we modified the interface specification of the system software. However, this modification of software does not indicate the new technological characteristics. But in this submission, Software Risk Analysis and Verification and Validation testing were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" to assure substantial equivalence.

As a result, we identified the level of concern associated with new device and provided documentation consistent with that level. Based on our risk analysis of software, the difference does not affect its safety and effectiveness.

Non-clinical Performance Testing

Since the Digital radiography system is exactly the same as the predicate device (K170332), the output image is substantially equivalent to the predicate device as long as the quality and profile of input X-ray are similar. The criteria for the connectability of X-ray generators are the compliance with IEC60601-1. This means that the quality and profile of X-ray generation are ensured and are substantially equivalent as long as the both X-ray generators comply with IEC60601-1. Since the subject device complies with IEC60601-1 and IEC60601-1-3(collateral standard), we concluded that the non-clinical image Performance and its data are substantially equivalent to the predicate device. Plus, the entire system performance is ensured by verification and validation of software, risk management, and the conformity of IEC standards. The verification and validation of software and risk management are documented and are attached to this submission. IEC standards including IEC60601-1, 60601-1-2 ensure the conformity of Electrical safety and Electromagnetic Compatibility performance by the testing based on IEC standards. Therefore, IEC standards and verification and validation of software and risk management ensure the safety and effectiveness of the subject device.

Clinical Performance Testing

Since the Digital radiography system is exactly the same as the predicate device (K170332), the output image is substantially equivalent to the predicate device as long as the quality and profile of input X-ray are similar. The criteria for the connectability of X-ray generators are the compliance with IEC60601-1. This means that the quality and profile of X-ray generation are ensured and are substantially equivalent as long as the both X-ray generators comply with IEC60601-1. Since the subject device complies with IEC60601-1 and IEC60601-1-3(collateral standard), we concluded that the clinical Performance and its data are substantially equivalent to the predicate device.

Radiation safety

New device and primary predicate device is substantially equivalent by their conformities of CFR and IEC60601-1-3.

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13) Conclusion

The non-clinical performance and the clinical performance are the substantially equivalent, which ensure the safety and effectiveness of the device. The hardware and software verification and validation demonstrate that new device should perform as intended in the specified use. Based on our risk analysis, the differences do not affect its clinical safety or effectiveness.

From the result of our risk analysis, software verification and validation, discussed above, it is our conclusion that,

- New device is substantially equivalent to the legally marketed predicate devices, K152244 RADspeed Pro manufactured by SHIMADZU CORPORATON and K170332 Digital Radiography CXDI-710C Wireless / Digital Radiography CXDI-810C Wireless.
- Additional Indication for Use of new device does not introduce any new safety and effectiveness concern.
- Therefore, new device is as safe, as effective, and performs as well as the predicate device(s).