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

July 15, 2016

SHIMADZU CORPORATION
% Mr. Don Karle
Manager, Customer Service
Shimadzu Medical Systems
20101 South Vermont Avenue
TORRANCE CA 90502-1328

Re: K152294
Trade/Device Name: FDR Visionary Suite
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: June 10, 2016
Received: June 16, 2016

Dear Mr. Karle:

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)*
K152294

Device Name
FDR Visionary Suite

Indications for Use *(Describe)*

The FDR Visionary Suite 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 FDR Visionary Suite enables radiographic or tomographic exposures 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 FDR Visionary Suite 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 Tomosynthesis option is intended to generate tomographic images of human anatomies. Tomosynthesis technique is used to produce a specific cross-sectional plane of the body by reconstruction of tomographic acquisition.

The device is intended to be used in hospitals, clinics, imaging centers, and/or other healthcare facilities by qualified/ trained professionals.

The device is not intended for mammographic 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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SECTION V: 510(k) Summary

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

1) Date of Submission

August 5th, 2015

2) Submitter

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5) Device

Name of Device	: FDR Visionary Suite
Common Name	: Digital 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	K093427	FDR ACSELERATE SYSTEM, DR-ID 200 FLAT PANEL DETECTOR	FUJIFILM CORPORATION
Secondary	K121499	FUJIFILM TOMOSYNTHESIS OPTION FOR FDR ACSELERATE STATIONARY X-RAY SYSTEM	FUJIFILM CORPORATION
Tertiary	K101686	FDR IMAGE STITCHING OPTION	FUJIFILM CORPORATION
Quaternary	K122454	FUJIFILM DUAL ENERGY SUBTRACTION (DES) SOFTWARE OPTION	FUJIFILM CORPORATION

No reference devices were used in this submission.

SECTION V: 510(k) Summary

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, K093427 FDR ACSELERATE SYSTEM, DR-ID 200 FLAT PANEL DETECTOR, K121499 FUJIFILM Tomosynthesis Option for FDR ACSELERATE STATIONARY X-RAY SYSTEM, K101686 FDR IMAGE STITCHING OPTION and K122454 FUJIFILM DUAL ENERGY SUBTRACTION (DES) SOFTWARE OPTION. The last three predicate devices are image processing options for the primary predicate device. All predicate devices are manufactured by FUJIFILM CORPORATION, Japan.

8) Device Description

The FDR Visionary Suite 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 device can be used in a wide range of applications of digital radiography. The device consists of an X-ray high voltage generator, X-ray tube unit, X-ray tube support, collimator and digital radiography system. The system can be configured with radiographic table and/or radiographic stand as well.

Major hardware components of new device are substantially equivalent to those of primary predicate device as below, even though some of components are optional in new device.

The difference is seen in below tables.

Tomosynthesis Comparison Table

	FDR Visionary Suite (New Device)	AcSelerate Tomosynthesis (K121499)
Available type	Stand, Table	Stand, Table
Shot Interval	200msec	200msec
Exposure number	Maximum 60 exposures	Maximum 60 exposures
Angulation	Table : Maximum 60 degree Wall stand : Maximum 40 degree	Table : Maximum 60 degree Wall stand : Maximum 40 degree
Slice Interval	Minimum 1mm	Minimum 1mm
Pixel Size	150um	150um
Processing	FUJIFILM Tomosynthesis processing (DR-ID 900CL) With Pre-Processing Unit (PPU)	FUJIFILM Tomosynthesis processing (DR-ID 300CL same as DR-ID 900CL) With Pre-Processing Unit (PPU)

Optionally, the device is also used to perform tomosynthesis radiography by two different reconstruction modes, e.g. Filtered Back-Projection (FBP) mode and Shift-and-Add (SA) mode. SA reconstructed images are intended to be used alongside FBP reconstructed images and not for stand-alone diagnostic purpose.

9) Intended Use

SECTION V: 510(k) Summary

The FDR Visionary Suite is a stationary X-ray system for taking general radiographic and tomographic 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 FDR Visionary Suite 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 FDR Visionary Suite enables radiographic or tomographic exposures 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 FDR Visionary Suite 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 Tomosynthesis option is intended to generate tomographic images of human anatomies. Tomosynthesis technique is used to produce a specific cross-sectional plane of the body by reconstruction of tomographic acquisition.

- The device is intended to be used in hospitals, clinics, imaging centers, and/or other healthcare facilities by qualified/trained professionals.

- The device is not intended for mammographic applications.

11) Comparison of Technological Characteristics with the predicate devices

At a high level, new device and its predicate devices 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

The following technological differences exist between new and its predicate devices.

- Use of software processing

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.

Software Verification and Validation Testing

Digital radiography system is using similar, but different software processing method. Therefore, 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

For the difference of software processing methods which is different from primary predicate device, we performed non clinical performance testing between new device and predicate devices, in accordance with the FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging(SSXI) Devices" issued on Aug. 6, 1999.

We conducted performance bench test and image quality evaluation to evaluate substantial equivalence of image processing technique to each predicate device respectively.

We also performed phantom tests using several different anatomical body phantoms.

For Dual Energy Subtraction, additional test report was submitted to assure the distinction of lesion overlying bones to calcification or tubercle shade.

For metal artifact reduction function of tomosynthesis option, we conducted performance testing.

The result indicates that FBP(filtered back-projection) mode of new device has a same level of metal artifact reduction capability as the mode with artifact reduction of its predicate device.

Considering all these aspects, the result of non-clinical performance data demonstrates substantial equivalence of new device to the predicate devices in aspect of image acquisition, image processing as well as image quality capabilities.

Clinical Performance Testing

The result of non-clinical bench testing demonstrates substantial equivalence to the predicate devices. Therefore, it is our understanding that clinical testing is not required in this case.

Radiation safety

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

13) Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that new device should perform as intended in the specified use. Based on our risk analysis and bench testing, the differences do not affect its clinical safety or effectiveness.

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

- New device is substantially equivalent to the legally marketed predicate devices, K093427 FDR ACSELERATE SYSTEM, DR-ID 200 FLAT PANEL DETECTOR, K121499 FUJIFILM Tomosynthesis Option for FDR ACSELERATE STATINOARY X-RAY SYSTEM, K101686 FDR IMAGE STITCHING OPTION and K122454 FUJIFILM DUAL ENERGY SUBTRACTION (DES) SOFTWARE OPTION.

- 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 or better than the predicate device(s).