March 28, 2024

Shimadzu Corporation
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
NAPLES, FL 34114

Re: K233719
Trade/Device Name: FDR Visionary Suite
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: January 26, 2024
Received: January 26, 2024

Dear Daniel Kamm:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233719

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K233719

SHIMADZU CORP.
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Kyoto City, JAPAN 604-8511
Date submitted: February 12, 2024
Prepared by: Koichi Kataoka, General Manager, Quality Assurance Department, Medical Systems Division
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1. **Identification of the Device:**
   Trade/Device Names: FDR Visionary Suite
   Regulation Number: 21CFR892.1680
   Regulation Name: Stationary X-Ray System
   Regulatory Class: II
   Product Code: KPR, MQB

2. **Equivalent legally marketed device: K152294**
   Trade/Device Name: FDR Visionary Suite
   Manufacturer: Shimadzu.
   Regulation Number: 21CFR892.1680
   Regulation Name: Stationary X-Ray System
   Regulatory Class: II
   Product Code: KPR, MQB

3. **Purpose of Submission: Modified Device. The fundamental technological features are the same for the subject and the predicate systems.**

4. **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 FDR Visionary Suite 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 FDR Visionary Suite 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. Optionally, the device is also used to perform tomosynthesis radiography by two different reconstruction modes. Filtered Back-Projection (FBP) mode is used to obtain a tomosynthesis image by performing back-projection after correcting the projection data. Shift Addition (SA) mode is used to obtain a tomosynthesis image at an arbitrary slice plane height by shifting each image according to projection angle of the tube based on the reconstruction height, and by applying image addition processing to them. FBP mode is generally recommended for all body parts. In case an artifact is observed at joints and other similar places, SA mode may remedy this artifact. In case metal artifact is obviously displayed. This description is the same as our predicate. Key technological characteristics of the main components: X-Ray Generators: Available in 80 kW, 65 kW, and 50 kW versions. Image receptor panels: More recently cleared versions of Fujifilm panels are now employed. Tomography remains completely unchanged, including the digital receptor panel DR-ID 911SE. Details are in the comparison table below.**

Software Description: These functions are unchanged:

- **DICOM Connection Software,**
  - **Basic Grayscale Print Management**
  - **Media Storage**
- **Image Processing Software**
  - **Multi-objective Frequency Processing**
  - **Grid Removal Processing**
  - **Shuttering Processing**
  - **Gradation Processing**
  - **Dynamic Range Control Processing**
  - **Tomographic Artifact Suppression Processing**
  - **Flexible Noise Control**
- **Function Software**
  - **Retake Analysis Software**

But the fundamental technological features are the same for the subject and the predicate systems. The changes are described in Section 6, below.

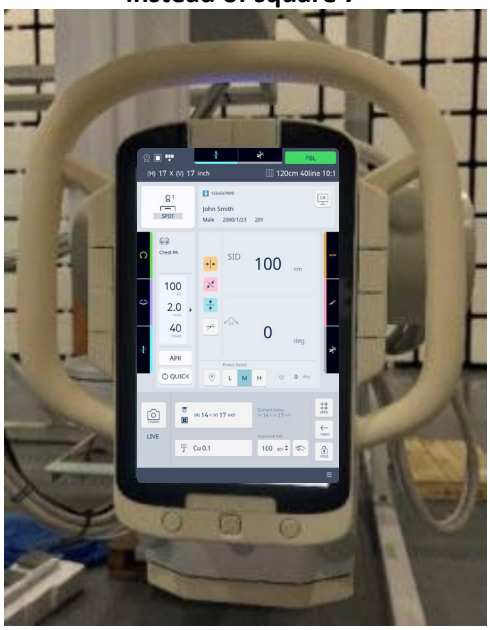
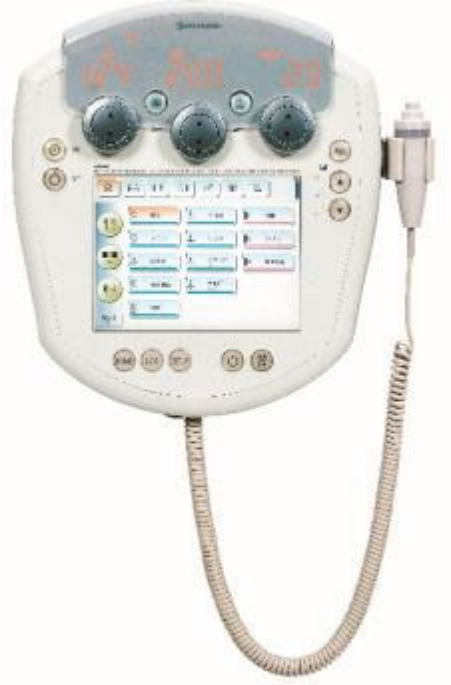
5. **Indications for Use: The FDR Visionary Suite is intended to generate digital or conventional radiographic images of the skull, spinal column, chest, abdomen, extremities, and other body parts of human anatomies in all routine radiography examinations. The FDR Visionary Suite enables radiographic 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.**

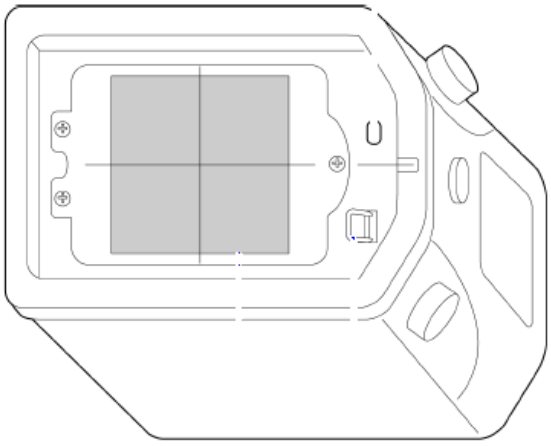
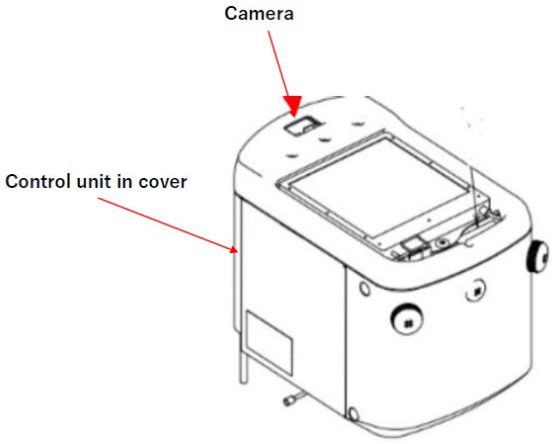
6. **Comparison of Technological Characteristics with the predicate device: At a high level, new device and its predicate device is based on the following same technological elements: Energy emission to the patient – X-ray Power requirement; Environmental requirement; Mechanism to generate X-ray; Mechanism to acquire, process and store image data; Use of the hardware components. The imaging components were replaced by more recently cleared digital x-ray receptor panels made by FUJIFILM. A detailed list is provided in the comparison table below.**
   The following technological differences exist between modified and its predicate device:
   A larger LCD display is employed in the collimator.
   A larger LCD display is employed in the generator control.
   A video camera has been added to the collimator to assist in patient positioning. Functions include: movie display, rotation, zooming, guideline overlay.
   A wireless remote control collimator control has been added.
   A wireless remote exposure control has been added.
   The software for the two touchscreens (Collimator and Generator Control) has been updated.
   Infrastructure: Change programming language (C ⇒ C, Golang, JavaScript)

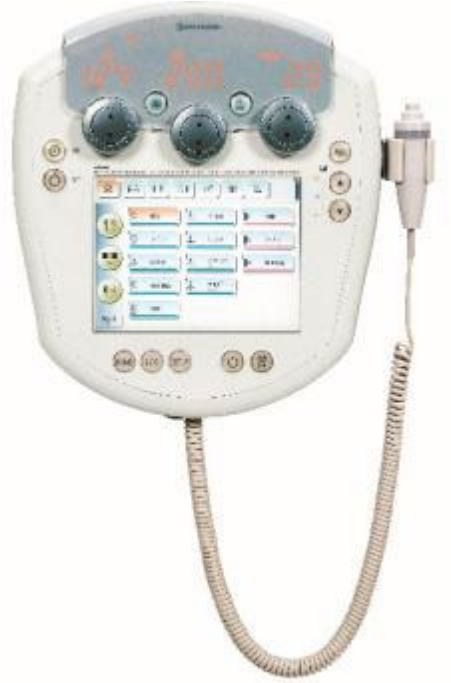
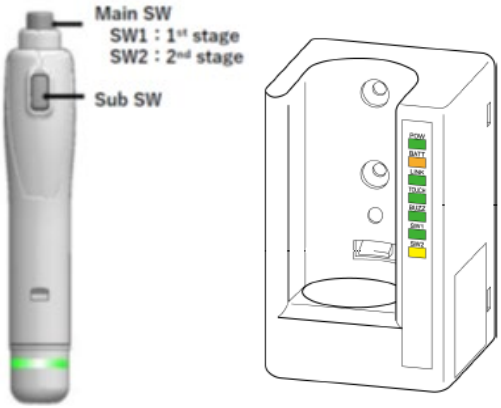
Architecture: Port to new OS (Real-time OS ⇒ Linux)
The software functionality remains unchanged.
The generator technical characteristics have not changed (kW, kV, mA, exposure times)
Imaging components: The updated versions of the FUJIFILM X-ray receptor panels (since 2015) have been employed except for the tomography digital panel which remains unchanged. All the imaging panels have 510(k) clearance as shown in the table below. The panels all use the same integration software which comes with the panel. The integration software, although updated, has the identical functionality to the predicate.

In conclusion, the main technological characteristics have not changed. The modified system has a more modern, updated "look."

Name of Modified Item	Predicate Device FDR Visionary Suite K152294	Modified Device FDR Visionary Suite K233719
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	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. UNCHANGED

Name of Modified Item	Predicate Device FDR Visionary Suite K152294	Modified Device FDR Visionary Suite K233719
Over-head Tube crane control		**CH-200(L) Touch screen now rectangular 12" instead of square 7"** 
Generator Console	**6.7" x 5" display, 640 x 480 pixels** 	**8.5"d x 5.4" display, 1280 x 800 pixels**  **Larger display, but same content**

Name of Modified Item	Predicate Device FDR Visionary Suite K152294	Modified Device FDR Visionary Suite K233719
Added Camera Option in Colli-mator	**R-300 Collimator Before Modification, no camera port** **Bottom View Shown** 	**Video Camera (HD resolution, 1280x720) added On front of R-300 Collimator, now called RC-300** **Bottom View shown** **Camera Functions Patient position, patient movement, plus: The following guide lines are superimposed on the camera image: Gridline, Exposure field, FPD effective area (Described in Section 10 of the System Users Manual)** 
Remote Controller	**Wired** 	**Wireless Remote Controller (Page 127 and 139 of the Tube Support User Manual)** **Shown in holder Closeup View** 

Name of Modified Item	Predicate Device FDR Visionary Suite K152294	Modified Device FDR Visionary Suite K233719
Exposure switch, part of Generator assembly	Wired Wired, shown attached to control panel 	Wireless Option: Battery operated Exposure Switch with holder, Described in Generator User Manual 
SOFTWARE	X	The software for the two touchscreens: (Colllimator and Generator Control) has been updated. Infrastructure: Change programming language (C ⇒ C, Golang, JavaScript) Architecture: Port to new OS , (Real-time OS ⇒ Linux) The software functionality remains unchanged.
Tomography Modes	SA mode : Reconstruction is performed using the standard back projection method. FBP mode : Reconstruction is performed using the Filtered Back Projection method	UNCHANGED
X-Ray Generator Power	Three available models: 50 kW (100 kV, 500 mA) 65 kW (100 kV, 650 mA) 80 kW (100 kV, 800 mA)	UNCHANGED
Generator kV	40 t0 150 kV	UNCHANGED
Exposure Times	81 positions, 0.001 to 10 sec	UNCHANGED
Current	(Depending on model) 10-500 mA (12 positions) 10-630 mA (12 positions) 10-800 mA (12 positions)	UNCHANGED

Name of Modified Item	Predicate Device FDR Visionary Suite K152294	Modified Device FDR Visionary Suite K233719
Filtration	Minimum total filtration IEC 60601-2-28:2017 1.7 mm Al/75 kV (Including added filter)	UNCHANGED
DR System	DR-ID 900.	UNCHANGED
FPD Flat panel detectors	For Tomography: DR-ID 911SE For radiography: DR-ID 601SE DR-ID 602SE DR-ID 611SE	For Tomography: DR-ID 911SE (SAME) For radiography: DR-ID 1201SE (K142003) DR-ID 1202SE (K142003) DR-ID 1211SE (K142003) DR-ID 1212SE (K142003) DR-ID 1831SE (K192932) DR-ID 1832SE (K192932) DR-ID 1811SE (K192932) DR-ID 1812SE (K192932) (All FPD models have previous clearance)

7. **Performance Testing Information: The radiation safety aspects of the device have not changed. The device remains compliant with the FDA Radiation Safety Standards. The following activities were performed as a result of the modifications to the device:**
   a. **The User Manuals were modified to reflect the changes detailed above.**
   b. **Software Validation was performed according to the FDA Guidance Documents: Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff (Basic Documentation Level) AND Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff.**
   c. **EMC and Electrical Safety Testing was performed according to these IEC Standards: Test Specification: EN 60601-1-2:2015 +A1:2021, IEC 60601-1-2:2014 +A1:2020; EN 60601-2-54:2009 +A1:2015 +A2:2019 clause 202; IEC 60601-2-54:2009 +A1:2015 +A2:2018 clause 202. Test Specification: IEC 60601-2-54:2009+A1+A2, IEC 60601-1:2005+A1, IEC 60601-1-3:2008+A1, IEC 60601-1-6:2010+A1, plus a Test Report for National Differences.**

8. **Conclusion: The non-clinical data supports the safety of the device and the hardware and software verification and validation demonstrate that new device should performs 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 K152294. The fundamental technological features are the same for the subject and the predicate systems. Therefore, new device is as safe, as effective, and performs as well as or better than the predicate device.**