October 12, 2023

Fujifilm Healthcare Americas Corporation
℅ Chaitrali Kulkarni
Sr. Regulatory Affairs Specialist
81 Hartwell Ave. Suite 300
LEXINGTON, MA 02421

Re: K231574
Trade/Device Name: Scenaria View 4.2
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: August 29, 2023
Received: August 29, 2023

Dear Chaitrali Kulkarni:

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 Radiologic 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231574

Device Name

Scenaria View 4.2

Indications for Use *(Describe)*

The SCENARIA View 4.2 system is indicated to acquire axial volumes of the whole body including the head. Images can be acquired in axial, helical, or dynamic modes. The SCENARIA View system can also be used for interventional needle guidance. Volume datasets acquired by a SCENARIA View system can be post-processed in the SCENARIA View system to provide additional information. Post-processing capabilities of the SCENARIA View software include, multi-planar reconstruction
(MPR), and volume rendering. Volume datasets acquired by a SCENARIA View system can be transferred to external devices via a DICOM standard interface. The Low Dose CT Lung Cancer Screening Option for the SCENARIA View system is indicated for using low dose CT for lung cancer screening. The screening must be conducted with the established program criteria and protocols that have been approved and published by a governmental body, a professional medical society, and/or FUJIFILM Healthcare Corporation.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

FUJIFILM
Value from Innovation

510(k) Summary

K231574

Submitter Information

Submitter:	FUJIFILM Healthcare Corporation 2-1, Shintoyofuta, Kashiwa-Shi, Chiba, JP 277-0804
Contact:	Chaitrali Kulkarni, Senior Regulatory Affairs Specialist
Telephone number:	(704)-517-4886
E-mail:	chaitrali.kulkarni@fujifilm.com
Date:	July 25, 2023

Subject Device Name

Trade/Proprietary Name:	SCENARIA View 4.2
Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Product Code	JAK, System, X-Ray, Tomography, Computed
Class	II
Panel	Radiology

Predicate Device Name

Predicate Device(s):	SCENARIA View 4.0 (K213829)
Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Product Code	JAK, System, X-Ray, Tomography, Computed
Class	II
Panel	Radiology

Indications for Use

The SCENARIA View 4.2 system is indicated to acquire axial volumes of the whole body including the head. Images can be acquired in axial, helical, or dynamic modes. The SCENARIA View system can also be used for interventional needle guidance. Volume datasets acquired by a SCENARIA View system can be post-processed in the SCENARIA View system to provide additional information. Post-processing capabilities of the SCENARIA View software include, multi-planar reconstruction (MPR), and volume rendering. Volume datasets acquired by a SCENARIA View system can be transferred to external devices via a DICOM standard interface. The Low Dose CT Lung Cancer Screening Option for the SCENARIA View system is indicated for using low dose CT for lung cancer screening. The screening must be conducted with the established program criteria and protocols that have been approved and published by a governmental body, a professional medical society, and/or FUJIFILM Healthcare Corporation.

Device Description

Function

The SCENARIA View 4.2 is a multi-slice computed tomography system that uses x-ray data to produce cross-sectional images of the body at various angles.

Scientific Concepts

The SCENARIA View 4.20system uses 128-slice CT technology, where the X-ray tube and detector assemblies are mounted on a frame that rotates continuously around the patient using slip ring technology. The solid-state detector assembly design collects up to 64 slices of data simultaneously. The X-ray sub-system features a high frequency generator, X-ray tube, and collimation system that produces a fan beam X-ray output. The system can operate in a helical (spiral) scan mode where the patient table moves during scanning. As the X-ray tube/detector assembly rotates around the patient, data is collected at multiple angles.

The collected data is then reconstructed into cross-sectional images by a high-speed reconstruction sub-system. The images are displayed on a Computer Workstation, stored, printed, and archived as required. The workstation is based on current PC technology using the Windows™ operating system.

Physical and Performance Characteristics

The SCENARIA View 4.2 system consists of a Gantry, Operator's Workstation, Patient Table, High- Frequency X-ray Generator, and accessories. The system performance is similar to the predicate device.

Performance Comparison

Evaluations were conducted for dose profile, image noise, Modulation Transfer Function (MTF), slice thickness and sensitivity profile, slice plane location, and CT dose index. The feature of having tilt for helical scan is a combination of features that are included in the predicate device and do not affect the diagnosis. Prospective ExamSplit is a modification of the image information and also does not affect the diagnosis. The AutoPositioning feature supports the operator's work prior to the CT examination, and does not affect the diagnosis.

The AutoPositioning function was verified to be working correctly through system testing. To ensure the AutoPositioning option was working correctly, various cases were tested to verify if the AutoPositioning function will show up as an option. The following case testing was performed:

- Install the software as an application added to the existing system that does not have AutoPositioning installed.
- Indicate the name of this software and the version number as the version information in an environment where AutoPositioning option is installed.
- Enable AutoPositioning function in an environment where AutoPositioning is already installed.
- Prohibit the AutoPositioning function when this software is not installed in an environment where the AutoPositioning option is not installed.

All test results performed as expected.

Verification and validation testing was performed on ExamSplit function as well to ensure it works as expected. A mock procedure was carried out during which ExamSplit function was turned ON and the scan was carried out as listed in the operation manual. The following criteria had to meet in order for the ExamSplit testing to pass:

- After scan, an automatic analysis queue for the main recon of the original inspection is registered and executed.
- After the multi-recon is completed, the automatic analysis queue for the original inspection multi-recon is registered and executed.
- After Exam Split execution is completed, an automatic analysis queue for PES is registered and executed.

- Exam Split starts running after scan, and Multi Recon starts running Exam Split after recon is completed

All testing passed the above requirements.

The evaluation results confirm the performance characteristics of the SCENARIA View 4.2 are comparable to the predicate device and support our conclusion that the subject system is substantially equivalent.

Device Technological Characteristics

A summary of the differences is listed in the following table.

Systems	SCENARIA View Subject Device	SCENARIA View (K213829) Predicate Device
Physical characteristics		
Gantry	There are no differences between the two systems.	
Detector	There are no differences between the two systems.	
X-ray Tube	There are no differences between the two systems.	
X-ray Generator	There are no differences between the two systems.	
Patient Table	There are no differences between the two systems.	
Display	There are no differences between the two systems.	

Systems	SCENARIA View Subject Device	SCENARIA View (K200498) Predicate Device
Image Storage	Storage type changed from hard disk to SSD. Size of raw data storage is reduced, max of raw data is not changed	
Scanning, Reconstruction	There are no differences between the two systems.	
Performance	There are no differences between the two systems.	
Dose Controls	There are no differences between the two systems.	
Dose Displays	There are no differences between the two systems.	
Features	The option to add tilt for helical scan was added. Exam split was improved by adding the ability to split time before and after the scan. New feature of AutoPositioning was added to the subject device.	

Therefore, based on a thorough analysis and comparison of subject device (SCENARIA View 4.2) and the predicate device, the technological characteristics do not impact safety and effectiveness.

Substantial Equivalence

A summary decision was based on a thorough analysis and comparison of the functions, scientific concepts, physical and performance characteristics, performance comparison and technological characteristics.

ITEM	OVERALL RATIONALE ANALYSIS
Gantry	No changes
Detector	No changes
X-ray Tube	No changes
X-ray Generator	No changes
Patient Table	No changes
Display	No changes
Image Storage	Storage type changed from hard disk to SSD. However, max number of Raw Data (6000 scan) is not changed.
Scanning, Reconstruction	No changes
Performance	No changes
Dose Controls	No changes
Dose Displays	No changes
Features	The option to add tilt for helical scan was added. Exam split was improved by adding the ability to split time before and after the scan. New feature of AutoPositioning was added to the subject device.

Therefore, based on a thorough analysis and comparison of the functions, scientific concepts, physical and performance characteristics, performance comparison and technological characteristics, the proposed SCENARIA View 4.2 is considered substantially equivalent to the currently marketed predicate device (SCENARIA View 4.0 (K213829)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

FUJIFILM
Value from Innovation

Summary of Non-Clinical Testing

This device complies with all applicable requirements for Dose Profile, Noise, Mean CT number and Uniformity, Spatial Resolution, Tomographic Section Thickness and Sensitivity Profile, Tomographic Plane Location, and CT dose index.

In addition, the SCENARIA View system is in conformance with the applicable parts of the following standards:

- AAMI ANSI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012

  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.0

  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-3 Edition 2.1

  Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
- IEC 60601-2-44 Edition 3.2

  Medical electrical equipment Part 2-44: particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography.
- IEC 62304 Edition 1.1

  Medical device software - Software life cycle processes
- NEMA XR 25 Computed Tomography Dose Check

Summary of Performance Testing

Testing Type	Rationale Analysis
Performance Testing - Bench	There is no change is the following performance issues: Dose Profile, Noise, Mean CT number and Uniformity, Spatial Resolution, Tomographic Section Thickness and Sensitivity Profile, Tomographic Plane Location, CT Dose Index.
Performance Testing - Clinical	N/A

Conclusions

FUJIFILM believes that, based on the information included in the submission, SCENARIA View 4.2 subject device is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the SCENARIA View 4.0 (K213829).