May 20, 2025

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

Re: K250370
Trade/Device Name: SCENARIA View Phase 5.0
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: May 7, 2025
Received: May 7, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*

K250370

Device Name

SCENARIA View Phase 5.0

Indications for Use *(Describe)*

The SCENARIA View 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 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.

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510(k) Summary

Contact Details

Applicant Name	FUJIFILM Corporation
Applicant Address	26-30, Nishiazabu 2-chome, Minato-ku, Tokyo 106-8620, JAPAN
Applicant Contact Telephone	(704)-517-4886
Applicant Contact	Chaitrali Kulkarni, Senior Regulatory Affairs Specialist
Applicant Contact Email	hcusregulatoryaffairs@fujifilm.com
Applicant Date	February 5, 2025

Subject Device Name

Device Trade Name	SCENARIA View Phase 5.0
Common Name	Computed tomography x-ray system
Classification Name	Computed tomography x-ray system
Regulation Number	892.1750
Product Code	JAK

Predicate Device Name

Predicate Device Trade Name	SCENARIA View 4.2
510(k) Number	K231574
Common Name	Computed tomography x-ray system
Classification Name	Computed tomography x-ray system
Regulation Number	892.1750
Product Code	JAK

Device Description Summary

The subject device SCENARIA View is a multi-slice CT 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.

The SCENARIA View system 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.

Compared to the predicate device referenced within this submission, the subject devices support the following modifications:

1) New features
   - AutoPose is an AI-based function that recognizes a specific body part in an image of localization scan and then automatically sets the scan range and the image reconstruction range.
   - RemoteRecon is a function of setting image reconstruction parameters that runs on the external personal computer (hereinafter referred to as “PC”) connected to the CT system.

2) Modified features
   - The maximum load capacity of patient table type has been increased from 250kg to 300 kg.
   - Motion corrected reconstruction is an image reconstruction feature that reduces motion artifacts. The feature has been modified to include applicability for chest examinations, which is a non-gated scan.
   - AutoPositioning is a feature that assist in positioning the patient by camera images. The feature has been modified to include additional 12 body parts (Head and Neck, Neck, C-spine, Heart, Chest-Abdomen, Chest-Upper Abdomen, Abdomen-Pelvis, Abdomen, Pelvis, T-spine, L-spine, T-L-spine), in addition to the 2 body parts (Head, Chest) of the predicate device, with scanogram ranges displayed according to the selected protocol.

Intended Use/Indications for Use

The SCENARIA View 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 Corporation.

The SCENARIA View system is intended for general populations.

Indications for Use Comparison

No difference in indications for use.

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Substantial Equivalence

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

Systems	Subject Device SCENARIA View Phase 5.0	Predicate Device SCENARIA View 4.2 (K231574)	Discussion of Difference
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	Types of maximum load capacity: 250kg, 300kg	Types of maximum load capacity: 250kg	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics. For safety, this item is controlled and tested according to same regulations and/or standards as the predicate device.
Operator's console	There are no differences between the two systems.		--
Scanning	There are no differences between the two systems.		--
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 Display	There are no differences between the two systems.		--
Features There are the following differences between the two systems.			
AutoPose	Yes	--	Note 1
RemoteRecon	Yes	--	Note 2
Motion corrected reconstruction	Supported body parts: Heart (Cardio Still Shot), Chest (Body Still Shot)	Supported body part: Heart (Cardio Still Shot)	Note 3
AutoPositioning	Supported body parts: Head, Chest, Head and Neck, Neck, C-spine, Heart, Chest-Abdomen, Chest-Upper Abdomen, Abdomen-Pelvis, Abdomen, Pelvis, T-spine, L-spine, T-L-spine	Supported body parts: Head, Chest	Note 4

Note 1:

AutoPose is an AI-based function that recognizes a specific body part in an image of scanogram and then automatically sets the scan range and the range from which an image is to be created. The difference in the above features and specifications do not constitute a new intended use. There are no significant changes in technological characteristics. For safety, this item is controlled and tested according to same regulations and/or standards as the predicate device.

Note 2:

The existing image reconstruction parameters are set on an external PC, and the execution of image reconstruction is requested to the CT system. The image reconstruction process is not changed. The difference in the above features and specifications do not constitute a new intended use. There are no significant changes in technological characteristics. For safety, this item is controlled and tested

according to same regulations and/or standards as the predicate device.

Note 3:

As one of the motion correction reconstruction features, body still shot for chest examination has been added. Body still shot is an image reconstruction feature that reduces motion artifacts. The basic algorithm of motion correction reconstruction has not changed, and the support part has been expanded. The difference in the above features and specifications do not constitute a new intended use. There are no significant changes in technological characteristics. For safety, this item is controlled and tested according to same regulations and/or standards as the predicate device.

Note 4:

The basic algorithm of AutoPositioning has not been changed and carry out the necessary verifications (intended use, functionality, safety) and increase the number of support parts. The difference in the above features and specifications do not constitute a new intended use. There are no significant changes in technological characteristics. For safety, this item is controlled and tested according to same regulations and/or standards as the predicate 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 subject device is considered substantially equivalent to the currently marketed predicate device in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

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Non-Clinical Tests Summary

21 CFR 1020.33(c)(g)

We generated bench data based on IEC61223-3-5.

We confirmed that the following items which we tested met the conditions of 21 CFR 1020.33(c) and (g): Spatial Resolution, Noise, Mean CT number and Uniformity, and Tomographic Section Thickness.

There are no changes in the following performance issues: Dose Profile, Sensitivity Profile, Tomographic Plane Location, and CT dose index.

This shows that the subject device has equivalent basic performance as the predicate device.

In addition, the subject device is in conformance with the applicable parts of the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-1-2 Edition 4.1
  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 2.2
  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

In addition, we performed the following bench tests.

300 kg load capacity patient table

Regarding the increase in load to 300 kg, we conducted standard tests for IEC60601-1 and IEC 60601-2-44, such as stop processing and dynamic loading, and confirmed that they conformed to the standards.

AutoPositioning

Methods

Compare the number of steps in the procedure for moving the patient on the patient table from the lowest position to the scanogram start position to see if the number of steps in the procedure can be reduced by comparing the conventional manual operation with the AutoPositioning operation.

Results

AutoPositioning improves workflow because it reduces the number of steps in the procedure and allows the patient to be moved to the scanogram start position with a single operation. AutoPositioning is the process for setting up the scanogram, and does not involve diagnostic imaging or diagnostic evaluation, so non-clinical bench testing is appropriate. This testing included evaluation of workflow improvements due to reduced steps identification. All tests met predefined objectives. Also, AutoPositioning can be fully tested on the engineering bench thus no additional clinical testing was required.

RemoteRecon

Methods

RemoteRecon function was tested to ensure it operates correctly by configuring conditions related to RemoteRecon and performing operations.

Results

It was confirmed that the RemoteRecon function (which includes setting existing image reconstruction parameters on an external PC and requesting the execution of image reconstruction on the CT system from the external PC) operates correctly under the configured conditions and performed operations.

AutoPose

Methods

AutoPose function was tested to ensure it operates correctly by configuring conditions related to AutoPose and performing operations.

Results

It was confirmed that the AutoPose function (which includes automatically setting the scan range and the image reconstruction range) operates correctly under the configured conditions and performed automatically setting.

Body Still Shot

Methods

Body Still Shot function was tested to ensure it operates correctly by configuring conditions related to Body Still Shot and performing image reconstruction.

Results

It was confirmed that the Body Still Shot function (which includes setting image reconstruction parameters and reconstructing images) operates correctly under the configured conditions and performed image reconstruction.

Clinical Tests Summary

AutoPose

Methods

Perform AutoPose performance test for each region. In the performance test, it is evaluated that the AutoPose function reduces the number of steps compared to the conventional manual operation. The performance test of AutoPose of Head (OM, SM, RB), Neck, Chest, Heart, Abdomen, Abdomen-Pelvis, Chest-Abdomen, Chest-Upper Abdomen, C-Spine, T-Spine, L-Spine, and T-L-Spine were performed by certified radiological technologists. The information about the data in the tests is shown below.

Region	Head	Neck	Chest	Heart
Number of cases	50	50	52	54
Collection site	Clinical sites in the USA			

Region	Abdomen	Abdomen-Pelvis
Number of cases	52	52
Collection site	Clinical sites in the USA	

Region	Chest-Abdomen	Chest-Upper Abdomen
Number of cases	50	
Collection site	Clinical sites in the USA	

Region	C-Spine	T-Spine	L-Spine	T-L-Spine
Number of cases	50	50	50	24
Collection site	Clinical sites in the USA			

Results

As the evaluation result, it was evaluated all the cases of AutoPose were able to reduce the number of steps compared with manual scan range setting. In addition, even if the scan range set by AutoPose is not set to the expected position, the maximum number of steps to be manually adjusted is the same with manual scan range setting. So, the AutoPose function is substantially equivalent to the predicate device.

However, AutoPose has not been evaluated in pediatric patients, and therefore, it is not intended for use in pediatric patients.

Body Still Shot

Methods

To evaluate the image quality of the reconstruction techniques, the images reconstructed by SCENARIA View system with and without the Body Still Shot were reviewed by Japanese M.D.

Results

Based on the review results, the function of Body Still Shot was evaluated to be able to obtain images of sufficient quality.

Conclusions

FUJIFILM believes that, based on the information included in the submission, the subject device SCENARIA View Phase 5.0 is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the predicate device SCENARIA View 4.2 (K231574).