April 26, 2024

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

Re: K233583
Trade/Device Name: FCT iSTREAM Phase 1
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: JAK
Dated: April 1, 2024
Received: April 1, 2024

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233583

Device Name
FCT iStream Phase 1

Indications for Use *(Describe)*
The FCT iStream 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 FCT iStream system can also be used for interventional needle guidance. Volume datasets acquired by an FCT iStream system can be post-processed in the FCT iStream system to provide additional information. Post-processing capabilities of the FCT iStream software include multi-planar reconstruction (MPR), and volume rendering. Volume datasets acquired by an FCT iStream system can be transferred to external devices via a DICOM standard interface.

The Low Dose CT Lung Cancer Screening Option for the FCT iStream 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.

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510(k) Summary

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:	January 22, 2024

Subject Device Name

Trade/Proprietary Name:	FCT iStream Phase 1
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 4.2 (K231574)
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 FCT iStream 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 FCT iStream system can also be used for interventional needle guidance. Volume datasets acquired by an FCT iStream system can be post-processed in the FCT iStream system to provide additional information. Post-processing capabilities of the FCT iStream software include multi-planar reconstruction (MPR), and volume rendering. Volume datasets acquired by an FCT iStream system can be transferred to external devices via a DICOM standard interface.

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Device Description

Function

The FCT iStream 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 FCT iStream X-ray source is designed to enable the continuous emission of fan-beam X-rays, and the solid state detector unit is positioned opposite the X-ray source to measure the intensity distribution of the X-rays. The total number of detector channels is 888 channels x 64 rows, and all of the rows are used as 64-slice portions. Note that the magnification factor of the X-ray system is 1.77 and that the width of the opening of each channel in the center of the measuring area is 0.6 mm. These factors, along with the focal spot size, affect spatial resolution.

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 FCT iStream 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 IntelliODM, iTilt and for features that were removed from the subject device to the predicate device (see table below).

Removed Features

1	Gantry tilt mechanism
2	Shuttle Scan and Helical Shuttle Scan
3	Adaptive Filter function (a part of Image analysis function)
4	Segmentation function (a part of Image analysis function)
5	Retouch function (a part of Image analysis function)
6	Image Analysis on external PC
7	Motion corrected reconstruction (Cardio Still Shot)
8	Assist in patient positioning using camera (AutoPositioning)

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

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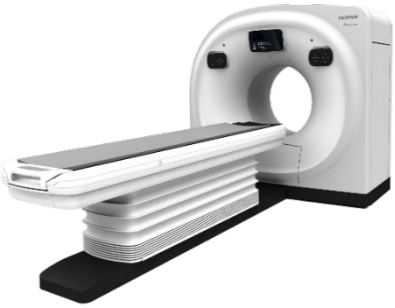
Device Technological Characteristics

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

Systems	FCT iStream Phase 1 Subject Device	SCENARIA View 4.2 (K231574) Predicate Device
Physical characteristics		
Gantry	The specifications of the device are different, the minimum scan time of this device is not as short as the predicate device. This change does not affect overall technological characteristics compared to the predicate device. This gantry does not have a tilt mechanism compared to the predicate device. If it is necessary to take a tilted image, it will use the iTilt function to create an equivalent MPR image. So it will not affect the effectiveness of the system. Also, this does not affect the safety of this device compared to the predicate device. The specifications of the device are different, the size and the weight of the gantry of this device are different from the predicate device. However, as the device weighs less and has a smaller footprint than the predicate device, we judge that these changes do not impact the intended use. The monitor in the center of the gantry is for display only. Since the information required for the intended use of the device is displayed.	
Detector	There are no differences between the two systems.	
X-ray Tube	The X-ray tube of this device is different from the predicate device only in heat capacity. The X-ray tube focal spot and general performance characteristics are the same as the predicate device.	
X-ray Generator	The specifications of the device are different, to match the performance specifications of this device and conforms to IEC 60601-2-44:2009+A1:2012+A2:2016 requirements for CT systems. The kVp and mA output of the device is comparable to the predicate device.	
Patient Table	The specifications of the device are different, the size and the weight of the table of this device are different from the predicate device. However, as the device weighs less and has a smaller footprint than the predicate device, we judge that these changes do not impact the intended use.	
Operator's console	Operator's console has a slight difference in SSD capacity of the predicate device, but the maximum number of storage images remains the same.	
Scanning, Reconstruction	The iTilt function uses MPR technology to create a tilt image immediately after scanning. This function uses the same technology as the existing MPR function, and does not affect overall technological characteristics compared to the predicate device.	
Performance	There is a difference in the Low-contrast mm at % ≤ 4 rads.	
Dose Controls	While this device is not equipped with a small bow-tie filter, the normal bow-tie filter provides generally equivalent performance to the predicate device and does not substantially impact the effectivity and safety of this device. Intelli IPV is no change in the algorithm, but the heat capacity is reduced from 7.5MHU to 6MHU, so the effect will be different. However, this does not impact the effectivity and safety of this device as compared to the predicate device.	
Features	IntelliODM is a feature that uses IntelliEC technology to reduce X-ray exposure from the patient's head, reducing direct radiation dose to sensitive organs.	

Therefore, based on a thorough analysis and comparison of subject device 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	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics. The gantry and detector design were based on the same technology as the predicate device. These subsystems have the same level of general effectiveness as the predicate device based on the performance test results. For safety, these items are controlled and tested according to same regulations and/or standards as the predicate device.
Detector	
X-ray Tube	
X-ray Generator	This item conforms to IEC 60601-2-44:2009+A1:2012+A2:2016 requirements for CT systems and has the same level of general effectiveness as the predicate device based on the performance test results. For safety, this item is controlled and tested according to same regulations and/or standards as the predicate device.
Patient Table	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics. The table travel and weight capacity characteristics are generally equivalent to the predicate device. For safety, this item is controlled and tested according to same regulations and/or standards as the predicate device.
Operator's console	Operator's console has a slight difference in capacity of the predicate device, but the maximum number of storage images remains the same. For safety, this item is controlled and tested according to same regulations and/or standards as the predicate device.
Scanning, Reconstruction	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics. The design criteria for these elements were set to allow comparable performance to the predicate device. The performance of these sub-systems does not substantially affect the effectivity and safety as compared to the predicate device.
Performance	There are no substantial differences in this category based on the performance test results.
Dose Controls	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics. For safety, these items are controlled and tested according to same regulations and/or standards as the predicate device.
Features	Different specifications do not constitute a new intended use. There are no significant changes in technological characteristics and the feature set of the device is generally equivalent to 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 FCT iStream Phase1 is considered substantially equivalent to the currently marketed predicate device (SCENARIA View 4.2 (K231574)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

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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 FCT iStream Phase 1 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	We generated bench data based on IEC61223-3-5. We confirmed that the items (Dose Profile, Spatial Resolution, Noise, Mean CT number and Uniformity, Tomographic Section Thickness and Sensitivity Profile, Tomographic Plane Location, CT dose index) which we tested met the conditions of 21 CFR 1020.33(c) or (g). This shows that FCT iStream Phase 1 has equivalent basic performance as the predicate device, SCENARIA View 4.2.
Performance Testing - Clinical	N/A

Conclusions

FUJIFILM believes that, based on the information included in the submission, FCT iStream Phase 1 subject device is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the SCENARIA View 4.2 (K231574).