Hitachi Healthcare Americas
℅ Mr. Aaron Pierce
Director, RA/QA
1959 Summit Commerce Park
TWINSBURG OH 44087

July 17, 2020

Re: K200498
Trade/Device Name: SCENARIA View
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: June 4, 2020
Received: June 8, 2020

Dear Mr. Pierce:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200498

Device Name
SCENARIA View

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 Hitachi.

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 K200498

Submitter Information

Submitter:	Hitachi Healthcare Americas 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
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Date:	June 4, 2020

Subject Device Name

Trade/Proprietary Name:	SCENARIA View
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 (K190841)
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

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Device Description

Function

The SCENARIA View 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 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.

Physical and Performance Characteristics

The SCENARIA View 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

A clinical evaluation comparison was conducted with the SCENARIA View system and the SCENARIA Phase 3 System (K150595) and found to be substantially equivalent as documented in Section 10 – Performance.

In addition, evaluations were conducted for dose profile, image noise, Modulation Transfer Function (MTF), slice thickness and sensitivity profile, slice plane location, and CT dose index as documented in Section 10 – Performance.

The evaluation results confirm the performance characteristics of the SCENARIA View 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 (K190841) Predicate Device
Physical characteristics		
Gantry	There are not differences between the two systems.	
Detector	There are not differences between the two systems.	
X-ray Tube	There are not differences between the two systems.	
X-ray Generator	There are not differences between the two systems.	

Systems	SCENARIA View Subject Device	SCENARIA View (K190841) Predicate Device
Patient Table	There are not differences between the two systems.	
Display	There are not differences between the two systems.	
Image Storage	There are not differences between the two systems.	
Scanning, Reconstruction	There are not differences between the two systems.	
Performance	There are not differences between the two systems.	
Dose Controls	There are not differences between the two systems.	
Dose Displays	There are not differences between the two systems.	
Features	The new Volume Shuttle Scan and HiMAR Plus features have been added.	

HiMAR Plus feature provides two strength levels as “standard” and “strong”, which can adjust the correction strength in raw data space.

Volume Shuttle Scan is an optional feature for alternating the forward and backward directions of the table, in the same scan range, while at the same time taking scan images and moving the table quickly.

Therefore, based on a thorough analysis and comparison of subject device (SCENARIA View) 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	There are no significant changes in the SCENARIA View from the predicate device which would affect safety or effectiveness.
Detector	
X-ray Tube	
X-ray Generator	
Patient Table	
Display	
Image Storage	
Scanning, Reconstruction	
Performance	
Dose Controls	
Dose Displays	
Features	

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 is considered substantially equivalent to the

currently marketed predicate device (SCENARIA View (K190841)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

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 60601-1-6 Edition 3.1

  Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-2-44 Edition 3.1

  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
- IEC 62366 Edition 1.1

  Medical devices - Application of usability engineering to medical devices
- NEMA XR 25 Computed Tomography Dose Check
- NEMA XR29 Standard Attributes on CT Equipment Related to Dose Optimization and Management

Summary of Clinical Testing

Hitachi has conducted a clinical image study to assess the image quality of the images reconstructed by using FBP and the two new features. (HiMAR Plus, Intelli IPV).

Conclusions

Hitachi believes that, based on the information included in the submission, SCENARIA View Ph 2 is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the SCENARIA View (K190841).