DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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Hitachi Medical Systems America, Inc. October 30, 2015
% Mr. Doug Thistlethwaite
Manager of Regulatory Affairs
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K150595
Trade/Device Name: HITACHI SCENARIA Phase 3 Whole-body X-ray CT System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: October 2, 2015
Received: October 6, 2015

Dear Mr. Thistlethwaite:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150595

Device Name
HITACHI SCENARIA Phase 3 Whole-body X-ray CT System

Indications for Use *(Describe)*
The SCENARIA Phase 3 system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages. The images can be acquired in either axial, helical, gated or dynamic modes.
The volume datasets acquired by the SCENARIA Phase 3 can be post processed by the SCENARIA Phase 3 to provide additional information. Post processing capabilities included in the SCENARIA Phase 3 software include CT angiography (CTA), Multi-planar reconstruction (MPR) and volume rendering.
Volume datasets acquired by the SCENARIA Phase 3 can be transferred to external devices via a DICOM standard interface.
The guideShot Option adds a remote in-room display and controls to support interventional imaging. The device output can provide an aid to diagnosis when used by a qualified physician.

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)

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Section 5

510(k) Summary

Submitter Information

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
Contact:	Douglas J. Thistlethwaite
Telephone number:	330-425-1313
Telephone number:	330-963-0749
E-mail:	thistlethwaited@hitachimed.com
Date:	February 26, 2015

Device Name

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
Trade/Proprietary Name:	SCENARIA Phase 3 Whole-body X-ray CT System
Predicate Device(s):	SCENARIA Phase 2 Whole-body X-ray CT System (K123509)

Device Intended Use

The SCENARIA Phase 3 system is indicated for head, whole body, cardiac and vascular X-ray Computed Tomography applications in patients of all ages. The images can be acquired in either axial, helical, gated or dynamic modes.

The volume datasets acquired by the SCENARIA Phase 3 can be post processed by the SCENARIA Phase 3 to provide additional information. Post processing capabilities included in the SCENARIA Phase 3 software include CT angiography (CTA), Multi-planar reconstruction (MPR) and volume rendering.

Volume datasets acquired by the SCENARIA Phase 3 can be transferred to external devices via a DICOM standard interface.

The guideShot Option adds a remote in-room display and controls to support interventional imaging. The device output can provide an aid to diagnosis when used by a qualified physician.

Device Description

Function

The SCENARIA Phase 3 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 Phase 3 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 Phase 3 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 and also found to be substantially equivalent.

A clinical evaluation comparison was conducted with the SCENARIA Phase 3 system and the SCENARIA Phase 2 System (K123509) and found to be substantially equivalent.

A rationale analysis was then conducted and the results are contained in Table 1.

Table 1 Performance Comparison Analysis

Testing Type	Rationale Analysis
Performance Testing - Bench	We generated bench data based on IEC61223-3-5. We confirmed that the items (Dose Profile, Noise, Mean CT number and Uniformity, Sparial Resolution, 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 SCENARIA Phase3 has equivalent basic performance as the predicate device, SCENARIA Phase2.
Performance Testing - Clinical	We provide five clinical image examples which we judged to be sufficient to judge a clinical usability. The five covered the general anatomy outlined in the indications for use and are comparable to the anatomy examples provided for the predicate.

The analysis confirms the performance characteristics of the SCENARIA Phase 3 system are comparable to the predicate device and support our conclusion that the SCENARIA Phase 3 system is substantially equivalent.

Device Technological Characteristics

The technological characteristics of the SCENARIA Phase 3 and the predicate device are listed in Table 2.

Table 2 Technological Characteristic Differences

ITEM	HITACHI SCENARIA PHASE 3	HITACHI SCENARIA PHASE 2 (K123509)	Difference Analysis
Gantry			
Geometry	Rotate-rotate with offset detector system, slip ring	Rotate-rotate with offset detector system, slip ring	No
Scan Time	0.35, 0.4, 0.5, 0.75, 1.0, 2.0 [s]	0.35, 0.4, 0.5, 0.75, 1.0, 2.0 [s]	No
X-ray Fan Beam Angle	51[deg]	51[deg]	No
Gantry Tilt	-30 to +30 [deg]	-30 to +30 [deg]	No
Gantry Aperture	750 [mm]	750 [mm]	No
Gantry Dimensions	2350 x 880 x 2030 [mm]	2350 x 880 x 2030 [mm]	No
Gantry Weight	2235 [kg]	2235 [kg]	No
Scan Localizer	Laser	Laser	No

ITEM	HITACHI SCENARIA PHASE 3	HITACHI SCENARIA PHASE 2 (K123509)	Difference Analysis
Detector			
Type	Solid state	Solid state	No
Number of Channels	888 [ch] (8ch reference)	888 [ch] (8ch reference)	No
Number of Rows	64	64	No
Number of Slices	64, 128 [slice/scan] (Axial)	64, 128 [slice/scan] (Axial)	No
X-ray Tube			
Anode Heat Storage	7.5 [MHU]	7.5 [MHU]	No
Dissipation Rate	1,386 [kHU/min]	1,386 [kHU/min]	No
Tube cooling	Cooling Fluid/air	Cooling Fluid/air	No
Tube focal spot	Dual 0.7 x 0.8, 1.2 x 1.4 [mm]	Dual 0.7 x 0.8, 1.2 x 1.4 [mm]	No
X-ray Generator			
kW Output	72 [kW]	72 [kW]	No
Max. Power Input	100 [kVA]	100 [kVA]	No
kVp Range	80, 100, 120, 140 [kVp[	80, 100, 120, 140 [kVp]	No
mA Range	10 to 600 [mA] @120kV, 72kW	10 to 600 [mA] @120kV, 72kW	No
Patient Table			
Range of Movement, Vertical	465 to 1050 [mm] (CT-WT-19)	465 to 1050 [mm] (CT-WT-19)	No
Range of Movement, Longitudinal	2110 [mm]	2110 [mm]	No
Range of Movement, Lateral	-80 to +80 [mm] (CT-WT-19)	-80 to +80 [mm] (CT-WT-19)	No
Scannable Range	175 cm	175 cm	No
Maximum Load Capacity	230 [kg]	230 [kg]	No
Display			
Monitor Type	24" LCD	24" LCD	No
Matrices, Pixels	1920 x 1200	1920 x 1200	No
Image Enlargements	Up to 9.99x	Up to 9.99x	No
Max. Slices Displayed at Once	25	25	No
Image Storage			
Hard Disk	250 [GB] (images), 750 [GB] (raw data)	250 [GB] (images), 750 [GB] (raw data)	No
Storage Images	200,000	200,000	No
Archival Storage (Media)	DVD-RAM, DVD-R/RW, CD-R/RW	DVD-RAM, DVD-R/RW, CD-R/RW	No
Scanning, Reconstruction			
Localization Scan	Real time	Real time	No
Localization Scan Length	150, 250, 350, 500, 750, 1000, 1250, 1500, 1750 [mm]	150, 250, 350, 500, 750, 1000, 1250, 1500, 1750 [mm]	No
Max. Scan Time	100 [s]	100 [s]	No
Helical Beam Pitch	0.58, 0.83, 1.08, 1.33, 1.58 @40mm Collimation	0.58, 0.83, 1.08, 1.33, 1.58 @40mm Collimation	No
Collimation	1.25, 5, 10, 15, 20, 40 [mm]	1.25, 5, 10, 15, 20, 40 [mm]	No
Reconstruction Matrix	512 x 512 [pix]	512 x 512 [pix]	No
Reconstruction FOVs	20 to 500 [mm]	20 to 500 [mm]	No
Slice Thickness	0.625, 1.0, 1.25, 2.5, 3.75, 5.0, 7.5, 10.0 [mm]	0.625, 1.0, 1.25, 2.5, 3.75, 5.0, 7.5, 10.0 [mm]	No
Range of CT numbers	-2000 to +4000 (13bit) -32768 to +32767 (16bit)	-2000 to +4000 (13bit) -32768 to +32767 (16bit)	No
Reconstruction Time	0.056 seconds per image or less	0.056 seconds per image or less	See 01
Performance			
High-contrast spatial resolution	0.35 [mm]	0.35 [mm]	No
Low-contrast resolution mm at % at ≤4 rads	2.5 [mm] @ 0.25%	2.5 [mm] @ 0.25%	No
10% MTF	14.7 [lp/cm]	14.7 [lp/cm]	No
50% MTF	12.2 [lp/cm]	12.2 [lp/cm]	No
Dose Controls			
Bow Tie Filter	Yes. Small / Normal	Yes. Small / Normal	No
Automatic Exposure Control	Yes. IntelliEC, IntelliEC Plus	Yes. IntelliEC	See 02

ITEM	HITACHI SCENARIA PHASE 3	HITACHI SCENARIA PHASE 2 (K123509)	Difference Analysis
Longitudinal Modulation	Yes	Yes	No
Angular Modulation	Yes	Yes	No
Iterative Reconstruction	Yes. Intelli IP Advanced Mode.	Yes. Intelli IP Advanced Mode	No
Maximum possible pitch with full image quality	1.58	1.58	No
Dose Displays			
CTDIv	Yes	Yes	No
DLP	Yes	Yes	No
Features			
Axial Scan	Yes	Yes	No
Helical Scan	Yes	Yes	No
Dynamic Scan	Yes	Yes	No
Predict Scan	Yes	Yes	No
ECG Retrospective Scan (Helical)	Yes	Yes	No
ECG Prospective Scan (Axial)	Yes	Yes	No
guideShot Scan	Yes	Yes	No
Automatic Exposure Control	Yes. IntelliEC	Yes. IntelliEC	No
Automatic Exposure Control considering the level of Iterative Reconstruction	Yes. IntelliEC Plus	No.	See 03
ECG Dose Modulation	Yes. IntelliEC Cardiac	No.	See 04
Adaptive Filter	Yes. Intelli IP Normal	Yes. Intelli IP Normal	No
Iterative Reconstruction	Yes. Intelli IP Advanced	Yes. Intelli IP Advanced	No
Injector Synchronization	Yes	Yes	No
Dose Check	Yes	Yes	No
Access Control	Yes	No	See 05
Automatic Cardiac Phase Search	Yes. CardioHarmony	Yes. CardioHarmony	No
Preview Scan	Yes	No	See 06
Double Slice at Axial Scan	Yes. Fine Recon	Yes. Fine Recon	No
Priority Recon.	Yes	No	See 07
Dose Report	Yes. Simple Dose Report	Yes. Simple Dose Report	No
DICOM	Yes	Yes	No
ID Reader	No	No	No
Exam Split	Yes	No	See 08
Multi-Planar Reconstruction (MPR)	Yes	Yes	No
Volume Rendering	Yes	Yes	No
CT Angiography (CTA)	Yes	Yes	No
Segmentation	Yes	Yes	No
Retouch	Yes	Yes	No
Quality Exam	Yes	No	See 09

The differences from the predicate device to SCENARIA Phase 3 are explained in Table 3.

Table 3 Analysis of Differences

Scanning, Reconstruction	
01	Image reconstruction time is reduced by enhancing usage efficiency of the image reconstruction system hardware.
Dose Controls	
02	This function had been added to SCENARIA Phase 3 by modifying IntelliEC installed in SCENARIA Phase 2. This function performs IntelliEC with previously factored-in noise reduction rate of Intelli IP Advanced.
Features	
03	This new feature function had been added by modifying IntelliEC installed in SCENARIA Phase 2. This function performs IntelliEC with previously factored-in noise reduction rate of Intelli IP Advanced.

04	This new feature function had been added to SCENARIA Phase 3. This feature modulates tube current corresponding to cardiac phases in ECG Retrospective Scan.
05	This new feature function had been added by modifying Data Security installed in SCENARIA Phase 2. This function monitors device performance in accordance with IEC62351-8 and NEMA XR-26.
06	This new feature displays an image at the scan position while scanning in Volume Scan. The system image performance is not affected, as shown in the results of design validation.
07	This new feature sets the priority of queue recon registration. The system image performance is not affected, as shown in the results of design validation.
08	This new feature splits the series of scanned images into multiple series. The system image performance is not affected, as shown in the results of design validation.
09	This new feature function had been added to SCENARIA Phase 3. This function monitors the system performance in accordance with IEC61223-3-5/IEC61223-2-6. The system image performance is not affected, as shown in the results of design validation.

Therefore, based on a thorough analysis and comparison of the SCENARIA Phase 3 and the predicate device, the technological characteristics do not impact safety and effectiveness.

Substantial Equivalence

A summary decision was based on analysis of Table 4

Table 4 Rationale Analysis: SCENARIA Phase 3 vs. Predicate

ITEM	Overall Rationale Analysis
Gantry	There are no functional differences in this item.
Detector	
X-ray Tube	
Patient Table	There are no functional differences in this item.
Display	There are no functional differences in this item.
Image Storage	There are no functional differences in this item.
Scanning, Reconstruction	
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.
Dose Displays	There are no functional differences in this item.
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.

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 Phase 3 is considered substantially equivalent to the currently marketed predicate device (SCENARIA Phase 2 Whole-body X-ray CT System K123509) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

Summary of Non-Clinical Testing

Non-Clinical Testing

The SCENARIA Phase 3 Whole-body X-ray CT System was subjected to the following laboratory testing:

- 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 3: 2007

  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 2.0 2008-01

  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 3.0 2009-02

  Medical electrical equipment Part 2-44: particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography.
- NEMA XR 25 Computed Tomography
  Dose Check
- NEMA XR26
  Access Controls for Computer Tomography: Identification, Interlocks, and Logs
- IEC 62304 First edition 2006-05, Medical device software - Software life cycle processes

In addition, the 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.

Summary of Clinical Testing

Clinical images were collected and analyzed, to ensure that images constructed by the SCENARIA Phase 3 Whole-body X-ray CT System meet user needs.

As a result of the analysis:

Testing Type	Rationale Analysis
Performance Testing - Clinical	We provide five clinical image examples which we judged to be sufficient to judge a clinical usability. The five covered the general anatomy outlined in the indications for use and are comparable to the anatomy examples provided for the predicate.

Conclusions

Hitachi believes that, based on the information included in the submission, SCENARIA Phase 3 Whole-body X-ray CT System is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the SCENARIA Phase 2 Whole-body X-ray CT System (K123509).