DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 18, 2017

Hitachi Healthcare Americas Corporation
% Mr. Douglas J. Thistlethwaite
Manager of Regulatory Affairs
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K171738
Trade/Device Name: Supria True64
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 26, 2017
Received: July 28, 2017

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,

Michael D. O'Hara For

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)*

K171738

Device Name
Supria True64

Indications for Use *(Describe)*

The Supria True64 system is indicated for head, whole body, and vascular X-ray Computed Tomography applications in patients of all ages. The images can be acquired in either axial, helical, or dynamic modes.
The volume datasets acquired by the Supria can be post processed by the system to provide additional information. Post processing capabilities included in the Supria software include CT angiography (CTA), Multi-planar reconstruction (MPR) and volume rendering.
Volume datasets acquired by the Supria 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Submitter Information

Submitter:	Hitachi Healthcare Americas 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
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Date:	April 18, 2017

Subject Device Name

Trade/Proprietary Name:	Supria True64
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):	HITACHI SUPRIA Whole-body X-ray CT System Phase 3 (K163528)
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

Device Intended Use

The Supria True64 system is indicated for head, whole body, and vascular X-ray Computed Tomography applications in patients of all ages. The images can be acquired in either axial, helical, or dynamic modes.

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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 Supria True64 is a multi-slice computed tomography system designed to perform multi-slice CT scanning supported by 64-detector technology. The system allows optimum clinical applications ranging from routine exams in response to the diversified circumstances in imaging whole body regions.

Scientific Concepts

The Supria True64 system uses 64-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 Supria True64 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

As part of our design validation performance comparison analysis was conducted to demonstrate continued conformance with a special control or recognized standard.

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

Table 1 Performance Comparison Analysis

Testing Type	Rationale Analysis
Validation Testing - Bench	There is no change about the following performance. Dose Profile, Noise, Mean CT number and Uniformity, Spatial Resolution, Tomographic Section Thickness and Sensitivity Profile, Tomographic Plane Location, CT dose index Therefore, we judged that Supria is substantially equivalent to the predicate.
Validation Testing - Clinical	We provide 3 kinds of clinical image example which we judged to be sufficient to judge a clinical usability.

The analysis confirms the performance characteristics of the Supria True64 are comparable to the predicate device and support our conclusion that the subject system is substantially equivalent.

Device Technological Characteristics

The technological characteristics of the Supria True64 and the predicate device are listed in Table 2.

Table 2 Technological Characteristic Differences

ITEM	Supria True64	HITACHI Supria PHASE 3 (K163528)	Difference
Gantry			
Geometry	Rotate-rotate with offset detector system, slip ring	Rotate-rotate with offset detector system, slip ring	No
Scan Time	0.75, 1.0, 1.5, 2.0 [s]	0.75, 1.0, 1.5, 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	1990 x 920 x 1842.5 [mm]	1990 x 920 x 1842.5 [mm]	No
Gantry Weight	1600 [kg]	1600 [kg]	No
Scan Localizer	Laser	Laser	No

ITEM	Supria True64	HITACHI Supria PHASE 3 (K163528)	Difference
Detector			
Type	Solid state	Solid state	No
Number of Channels	880 [ch] (16 slice) 888 [ch] (64 slice)	880 [ch] (8ch reference)	See 01
Number of Rows	16 (16 slice) 64 (64 slice)	16	
Number of Slices	16 [slice/scan] (Axial) (16 slice) 64 [slice/scan] (Axial) (64 slice)	16 [slice/scan] (Axial)	
X-ray Tube			
Anode Heat Storage	5 [MHU]	5 [MHU]	No
Dissipation Rate	470 [kHU/min]	470 [kHU/min]	No
Tube cooling	Oil/air	Oil/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	System Maximum 48[kW] / Generator Maximum 51 [kW]	System Maximum 48[kW] / Generator Maximum 51 [kW]	No
Max. Power Input	75 [kVA]	75 [kVA]	No
kVp Range	80, 100, 120, 140 [kVp]	80, 100, 120, 140 [kVp]	No
mA Range	10 to 400 [mA] @120kV, 48kW	10 to 400 [mA] @120kV, 48kW	No
Patient Table			
Range of Movement, Vertical	450 to 1000 [mm] (CT-WT-21)	450 to 1000 [mm] (CT-WT-21)	No
Range of Movement, Longitudinal	1910 [mm] (CT-WT-21)	1910 [mm] (CT-WT-21)	No
Range of Movement, Lateral	N/A	N/A	No
Scannable Range	155 cm	155 cm	No
Maximum Load Capacity	227 [kg]	227 [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	110 [GB] (images), 200 [GB] (raw data) (16 slice) 800 [GB] (raw data) (64 slice)	110 [GB] (images), 200 [GB] (raw data)	See 02
Storage Images	200,000	200,000	No
Archival Storage (Media)	DVD-R/RW, CD-R/RW	DVD-R/RW, CD-R/RW	No

ITEM	Supria True64	HITACHI Supria PHASE 3 (K163528)	Difference
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	0.56, 0.81, 1.06, 1.31, 1.56 (16 slice) 0.58, 0.83, 1.08, 1.33, 1.58 (64 slice)	0.56, 0.81, 1.06, 1.31, 1.56	See 03
Collimation	1.25, 5, 10, 15, 20 [mm]	1.25, 5, 10, 15, 20 [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	0.1 seconds per image or less	0.1 seconds per image or less	No
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. Normal	Yes. Normal	No
Automatic Exposure Control	Yes. IntelliEC	Yes. IntelliEC	No
Longitudinal Modulation	Yes	Yes	No
Angular Modulation	Yes	Yes	No
Iterative Reconstruction	Yes. Intelli IP Advanced, Intelli IP Quick	Yes. Intelli IP Advanced, Intelli IP Quick	No
Maximum possible pitch with full image quality	1.56 (16 slice) 1.58 (64 slice)	1.56	See 03
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)	No	No	No
ECG Prospective Scan (Axial)	No	No	No
guideShot Scan	Yes	Yes	No

ITEM	Supria True64	HITACHI Supria PHASE 3 (K163528)	Difference
Automatic Exposure Control	Yes	Yes	No
Automatic Exposure Control using Iterative Reconstruction	No	No	No
ECG Dose Modulation	No	No	No
Adaptive Filter	No	No	No
Iterative Reconstruction	Yes. Intelli IP Advanced, Intelli IP Quick	Yes. Intelli IP Advanced, Intelli IP Quick	No
Injector Synchronization	Yes	Yes	No
Dose Check	Yes	Yes	No
Access Control	Yes	Yes	No
Automatic Cardiac Phase Search	No	No	No
Preview Scan	No	No	No
Double Slice at Axial Scan	No	No	No
Priority Recon.	No	No	No
Dose Report	Yes. Simple Dose Report	Yes. Simple Dose Report	No
DICOM	Yes	Yes	No
ID Reader	Yes	Yes	No
Exam Split	Yes	Yes	No
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	Yes	No
HiMAR	Yes	Yes	No
Orbit synchronization scan	Yes	Yes	No
Off-time mode	Yes	Yes	No
On-time standby	Yes	Yes	No
Shutter Scan Reduction	Yes	Yes	No

The differences from the predicate device to Supria 64 are explained below table.

Detector	
01	The 64 lines detector is added.
Image Storage	
02	Raw data disk for 64 slices is added because the data amount for each raw data of 64 slices is .bigger than 16 slices.
Dose Controls	
03	Helical Beam Pitch is fine-tuned for 64 lines.

Therefore, based on a thorough analysis and comparison of Supra 64 and the predicate device, the technological characteristics do not impact safety and effectiveness.

Substantial Equivalence

A summary decision was based on analysis of Table 3.

Table 3 Rationale Analysis: Supria vs. Predicate

ITEM	Overall Rationale Analysis
Gantry	There are no significant changes in technology characteristics, hardware, and software from the predicate device, HITACHI Supria PHASE 3 (K163528).
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 Supria True64 Whole-body X-ray CT System is considered substantially equivalent to the currently marketed predicate device (SUPRIA Whole-body X-ray CT System (K163528)) 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.

Noise, Mean CT number, Uniformity and Spatial Resolution test results for the Supria True64 were compared to results from the Supria PHASE 3 (K163528. Our findings determined the systems to be equivalent. The summary report on these findings is provided in this submission.

In addition, the Supria True64 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 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

Summary of Clinical Testing

As part of design validation, Hitachi has provided 3 kinds of clinical image examples which we judged to be sufficient to judge a clinical usability.

In addition, a comparative evaluation was conducted of via FBP and Iterative Reconstruction. It resulted in finding the images from the Supria True64 realized both low dose and high quality through reduction of image noise and artifacts.

Conclusions

Hitachi believes that, based on the information included in the submission, Supria True64 Whole-body X-ray CT System is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the SUPRIA Whole-body X-ray System Phase 3 (K163528).