DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 3, 2017

Hitachi Medical Systems America, Inc.
% Mr. Doug Thistlethwaite
Manager of Regulatory Affairs
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K163528
Trade/Device Name: HITACHI Supria Whole-body X-ray CT System Phase 3
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: December 9, 2016
Received: December 16, 2016

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,

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)*

K163528

Device Name

HITACHI Supria Whole-body X-ray CT System Phase 3

Indications for Use *(Describe)*

The Supria 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# Section 5

# 510(k) Summary

## Submitter Information

| | |
|---|---|
| Submitter: | Hitachi Medical Systems America, Inc.<br>1959 Summit Commerce Park<br>Twinsburg, Ohio 44087-2371 |
| Contact: | Douglas J. Thistlethwaite |
| Telephone number: | 330-425-1313 |
| Telephone number: | 330-963-0749 |
| E-mail: | thistlethwaited@hitachimed.com |
| Date: | November 1, 2016 |

## Subject Device Name

| | |
|---|---|
| Trade/Proprietary Name: | HITACHI Supria Whole-body X-ray CT System Phase 3 |
| 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 w/guideShot Option (K161748) |
| 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 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.

## Device Description

### *Function*

The Supria is a multi-slice computed tomography system designed to perform multi-slice CT scanning supported by 16-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 system uses 16-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 16 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 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 Supria Phase 3 system and the SUPRIA w/guideShot Option (K161748) and found to be substantially equivalent.

There is no change in the performance of the system in regards to Dose Profile, Noise, Mean CT number and Uniformity, Spatial Resolution, Tomographic Section Thickness and Sensitivity Profile, Tomographic Plane Location, and CT dose index.

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 | Hitachi judged that Supria Whole-body X-ray CT System Phase 3is substantially equivalent to the predicate. |
| Performance Testing - Clinical | Hitachi has provided clinical images demonstrating the image quality of Intelli IP Quick and HiMAR features and validated by a physician. |

The analysis confirms the performance characteristics of the Supria Whole-body X-ray CT System Phase 3 are comparable to the predicate device and support our conclusion that the Phase 3 system is substantially equivalent.

## Device Technological Characteristics

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

Table 2 Technological Characteristic Differences

| ITEM | HITACHI Supria Whole-body X-ray CT System Phase 3 | HITACHI SUPRIA w/guideShot Option (K161748) | 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 | HITACHI Supria Whole-body X-ray CT System Phase 3 | HITACHI SUPRIA w/guideShot Option (K161748) | Difference |
|---|---|---|---|
| **Detector** | | | |
| Type | Solid state | Solid state | No |
| Number of Channels | 880 [ch] (8ch reference) | 880 [ch] (8ch reference) | No |
| Number of Rows | 16 | 16 | No |
| Number of Slices | 16 [slice/scan] (Axial) | 16 [slice/scan] (Axial) | No |
| **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) | 110 [GB] (images), 200 [GB] (raw data) | No |
| Storage Images | 200,000 | 200,000 | No |
| Archival Storage (Media) | DVD-R/RW, CD-R/RW | 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 | 0.56, 0.81, 1.06, 1.31, 1.56 | 0.56, 0.81, 1.06, 1.31, 1.56 | No |
| Collimation | 1.25, 5, 10 [mm] | 1.25, 5, 10 [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 |

| ITEM | HITACHI Supria Whole-body X-ray CT System Phase 3 | HITACHI SUPRIA w/guideShot Option (K161748) | Difference |
|---|---|---|---|
| Range of CT numbers | -2000 to +4000 (13bit)<br>-32768 to +32767 (16bit) | -2000 to +4000 (13bit)<br>-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 |
| Maximum possible pitch with full image quality | 1.56 | 1.56 | 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) | No | No | No |
| ECG Prospective Scan (Axial) | No | No | No |
| guideShot Scan (option) | Yes | Yes | No |
| 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 Quick | Yes. Intelli IP Advanced | See 01 |
| 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 |

| ITEM | HITACHI Supria Whole-body X-ray CT System Phase 3 | HITACHI SUPRIA w/guideShot Option (K161748) | Difference |
|---|---|---|---|
| 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 |
| Iterative Reconstruction | Yes. Intelli IP Quick | Yes. Intelli IP Advanced | See 01 |
| HiMAR | Yes | No | See 02 |
| Orbit synchronization scan | Yes | No | See 03 |
| Off-time mode | Yes | No | See 04 |
| On-time standby | Yes | No | See 05 |
| Shutter Scan Reduction | Yes | No | See 06 |

The differences from the predicate device to Supria Whole-body X-ray CT System Phase 3 are explained in Table 3.

Table 3 Analysis of Differences

| Features | |
|---|---|
| 01 | Intelli IP Quick: Intelli IP Quick is a faster noise reduction processing technique as compared to Intelli IP. |
| 02 | HiMAR: HiMAR reduces lack of photon caused by X-ray going through a highly absorptive body such as metals and a metal artifact caused by beam hardening. |
| 03 | Orbit synchronization scan: By using the orbit synchronization, the orbit of the volume scan multiple sequences can be combined and differences can be easily extracted by comparing each image together. |
| 04 | Off-time mode: The power consumption of the detector system is saved and noise is reduced when the power of the CT system is off. According to the usage of the system, the starting time can be registered. |
| 05 | On-time standby: During operation of the CT system, The power consumption under the standby condition is saved and noise is reduced. |
| 06 | Shutter Scan Reduction: The number of shutter scans was reduced. |

Therefore, based on a thorough analysis and comparison of the Supria Whole-body X-ray CT System 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: Supria vs. Predicate

| ITEM | Overall Rationale Analysis |
|---|---|
| Gantry | Based on that there are no significant differences from the predicate device, Hitachi judges that the Supria Whole-body X-ray CT System Phase 3 device has no additional issues with safety and effectiveness. |
| Detector | |
| X-ray Tube | |
| X-ray Generator | |
| Patient Table | |
| Display | |
| Image Storage | |
| Scanning, Reconstruction | |
| Performance | |
| Dose Controls | |
| Dose Displays | |
| Features | Based on results of design inspection as confirmed in the Declaration of Conformity, Hitachi judges that the Supria Whole-body X-ray CT System Phase 3 device has no additional issues with safety and effectiveness. |

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 Whole-body X-ray CT System Phase 3 is considered substantially equivalent to the currently marketed predicate device (SUPRIA w/guideShot Option (K161748)) in terms of design features, fundamental scientific technology, indications for use, and safety and effectiveness.

## Summary of Non-Clinical Testing

The Supria 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

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

Using the 2 new features, clinical images were collected and analyzed, to ensure that images constructed by the Supria Whole-body X-ray CT System meet user needs.

As a result of the analysis:

| Testing Type | Rationale Analysis |
|---|---|
| Performance Testing - Clinical | Hitachi has provided clinical images demonstrating the image quality of Intelli IP Quick and HiMAR features and validated by a physician. |

## Conclusions

Hitachi believes that, based on the information included in the submission, Supria Whole-body X-ray CT System Phase 3 is substantially equivalent with respect to hardware, base elements of the software, safety, effectiveness, and functionality to the SUPRIA w/guideShot Option (K161748).