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

May 16, 2018

Re: K180901
Trade/Device Name: Low Dose CT Lung Cancer Screening Option
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: April 4, 2018
Received: April 6, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180901

Device Name
Low Dose CT Lung Cancer Screening Option

Indications for Use *(Describe)*

The Low Dose CT Lung Cancer Screening Option for the SCENARIA and SUPRIA CT systems 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.
Some examples of published articles can be found at the American College of Radiology® (ACR) website:

- ACR–SCBT-MR–SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT) Res. 10 – 2013
- ACR–STR Practice Parameter for the Performance and Reporting of Lung Cancer Screening Thoracic Computed Tomography (CT) Res. 4 – 2014
- Lung Cancer Screening Technical Specifications
- Lung Cancer Screening Resources

In addition, examples of published articles can be found at the American Association of Physicists Medicine (AAPM) website:

- Lung Cancer Screening CT Protocols Version 4.0, 02/23/16
- AAPM Report No. 96: The Measurement, Reporting, and Management of Radiation Dose in CT

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."

Submitter Information

Submitter:	Hitachi Healthcare Americas 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@hitachihealthcare.com
Date:	April 6, 2018

Subject Device Name

Trade/Proprietary Name:	Low Dose CT Lung Cancer Screening Option
Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Product Code	90-JAK, System, X-Ray, Tomography, Computed
Class	II
Panel	Radiology

Predicate Device Name(s)

Trade/Proprietary Name:	Philips Multislice CT System with Low Dose CT Lung Cancer Screening K153444 (Philips Brillance CT 64-channel)
Regulation Number:	21 CFR 892.1750
Regulation Name:	Computed tomography x-ray system
Product Code	90-JAK, System, X-Ray, Tomography, Computed
Class	II
Panel	Radiology

Device Intended Use

The Low Dose CT Lung Cancer Screening Option for the SCENARIA and SUPRIA CT systems 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.

Some examples of published articles can be found at the American College of Radiology® (ACR) website:

- ACR–SCBT-MR–SPR Practice Parameter for the Performance of Thoracic Computed Tomography (CT) Res. 10 – 2013
- ACR–STR Practice Parameter for the Performance and Reporting of Lung Cancer Screening Thoracic Computed Tomography (CT) Res. 4 – 2014
- Lung Cancer Screening Technical Specifications
- Lung Cancer Screening Resources

In addition, examples of published articles can be found at the American Association of Physicists Medicine (AAPM) website:

- Lung Cancer Screening CT Protocols Version 4.0, 02/23/16
- AAPM Report No. 96: The Measurement, Reporting, and Management of Radiation Dose in CT

Device Description

There are not any functional, performance, feature, or design changes required for the CT systems which the option is applied:

- SCENARIA Phase 3 Whole-Body X-ray CT System K150595
- SUPRIA Whole-body X-ray CT System Phase 3 K163528

Because neither of the CTs will require hardware or software modifications the subject device will include:

- Three reference LCS protocols (small, average, large patient) for each CT System
- Protocols will be loaded onto the system, therefore there will be no need for installation instructions
- Low Dose CT Lung Cancer Screening Option instruction manual

The reconstruction method for the LCS protocols is Filtered Back Projection with no iterative reconstruction method. The reconstruction algorithm used was a 21 Lung which is common to demonstrate lung tissues nodules and other lung pathology.

In addition, Beam Hardening Correction is utilized in the reconstruction process. The beam hardening correction applied to the lung reconstruction algorithm corrects image quality degradation due to radiation hardening caused by metals and other dense subject matter such as shoulders, etc. Hitachi does not apply any other tools or software in the reconstruction process.

Physical and Performance Characteristics

There are not any functional, performance, feature, or design changes required for the CT systems onto which the Option is applied.

Device Technological Characteristics

The LCS feature consists of 3 protocols (small, average, large patient) for both CT systems. There is no new technology in regards to these protocols or their operation. The CT systems can execute these protocols without modification of the device.

The protocols were developed to take advantage of the systems slice thickness, number of slices per rotation, faster rotational speed, and dose reduction features from as a result of NEMA XR25. The protocols did not pose new questions related to safety and effectiveness.

Substantial Equivalence

Determination of substantial equivalence of the new LCS feature to the predicate devices was further evaluated on the bench. The measurements conducted during this comparison include:

- Contrast to noise ratio (CNR) for the test materials for all scanners.
- Mean and deviation of CT numbers for the 6 materials and the background material
- Repeatability (deviation of the CNR measurements over many repetitions for one representative slice)
- Uniformity (variation of CNR and/or mean CT numbers over a range of slices), taking care to avoid the ends of the contrast cylinders. We found that using several slices provided usable measurements while avoiding end effects of the contrast cylinders.
- Repetitions and numbers of slices used:
    - SUPRIA and SCENARIA scanners: 15 repetitions one slice, 15 slices one study
    - Philips scanner: 17 repetitions one slice, 25 slices one study
- Analysis was done using MATLAB

Substantial equivalence was determined by assessing the following parameters in relation to its impact and relationship to lung cancer screening.

Image Quality Metric CTQs	Reason for Inclusion
CT number accuracy	In a low signal situation such as with low dose LCS, the CT number measured in a nodule may be compromised. In LCS, the CT number may be a reference against potentially calcified nodules.
CT number uniformity	In a low signal situation such as with low dose LCS, maintaining sufficient CT number uniformity throughout the lung and various structures is important for more robust detectability of the nodules. Uniformity is needed to maintain CT number separation between structures.
Image noise (standard deviation)	As dose is reduced, background noise in the image increases. If this noise becomes too large, nodule detectability and sizing measurement may be compromised.
Visual Resolution/Image Artifact	This relates to the evaluation of images to assess their visual resolution using high contrast bar patterns and evaluation of the degree of artifacts (e.g. low signal streaks, beam hardening). These tests are relevant because of the high contrast detection task of relatively small objects for this application. Streak or beam hardening artifacts may obscure pathology and affect CT number accuracy.
Contrast to Noise (CNR)	Sufficient Contrast-to-Noise is needed to detect solid and non-solid nodules in the lung. This metric is similar to SNR but accounts for the contrast between an object and the background. GE believes this is the primary figure of merit to evaluate nodule detectability.

In order to demonstrate the substantial equivalence in the performance of the subject devices, a comparison of the above table of IQ metrics was performed using systems specifications and the results from tests conducted for the 510(k) submissions. As a result it was found that they were substantially equivalent.

Summary of Non-Clinical Testing

Hitachi has conducted extensive testing on the SCENARIA and SUPRIA CT systems in regards to LCS and additional testing with a similar level of detail was conducted on the Philips Brillance CT 64-channel. In addition, a comparison study was conducted between the Hitachi systems and the Philips system.

Hitachi Healthcare Americas has:

- Demonstrated that CT numbers for all scanners with all filter / recon combinations for the two Hitachi scanners match each other and match the Philips comparison unit to within ~ 3 Hounsfield numbers.
- Demonstrated that CNR is linearly related among the two Hitachi scanners, and also with the Philips comparison unit.
- Demonstrated that the variation (standard deviation) of CNR for the phantom test objects is in the range of 6%-8% among the two Hitachi scanners, and also for the Philips comparison unit.
- Demonstrated that the visibility of small high contrast objects (simulated blood vessels in this phantom) is comparable for all filter / recon combinations among the two Hitachi scanners, and for the Philips comparison unit.

Summary of Clinical Testing

Hitachi believes that there is sufficient evidence in the published literature and coverage decisions of the safety and effectiveness of the LCS feature when performed on a pre-defined high risk group, according to a pre-defined screening program that includes dose targets. Reference papers, clinical trials, medical professional guidelines, and governmental body review and recommendations form the clinical evidence that establishes the requisite safety and effectiveness.

The I-ELCAP paper from October 2006 published the 10-year results in the New England Journal of Medicine; the research includes over 31,000 patients who are considered to have a high risk of lung cancer. It concluded that patients who were diagnosed with lung cancer on annual CT screening have an estimated cure rate of 80% The research showed that when cancers are found at the earliest stage and are promptly removed with surgery, patients have a 92% chance of being cured; 85% of the patients who were diagnosed with annual screening had this curable, early-stage cancer.

The National Lung Screening Trial (NLST) demonstrated that LCS in pre-determined high risk populations has a net benefit, including 20% reduction in lung cancer mortalities, and an all-cause mortality reduction of 6.7% compared to an X-ray screening program.

The referenced clinical trials and publications include the prerequisite risk/benefit/harms analysis. They have been thoroughly and comprehensively reviewed as part of the USPSTF and CMS decision making. Additionally, there are currently at least nine Medical Professional Societies Providing Guidelines and/or Endorsements for LDCT Lung Cancer Screening.

Therefore, Hitachi has determined that additional clinical data for our LCS feature is not needed and that comparative phantom analysis is sufficient to demonstrate substantial equivalence.

Conclusions

In regards to the comparison of the SUPRIA and SCENARIA to the Philips Brilliance 64 (predicate device), Hitachi has confirmed that the:

- CT numbers for all scanners are very nearly the same
- CNR is linearly related for all scanner/recon combinations
- Variation of CNR is about the same for all the scanner/recon combinations
- Visibility of small high contrast objects (simulated blood vessels) is comparable for all scanner / recon combinations