DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 28, 2015

GE Medical Systems, LLC
% Mr. John Jaeckle
Chief Regulatory Affairs Strategist
3000 North Grandview Blvd.
WAUKESHA WI 53188

Re: K151372
Trade/Device Name: Low Dose CT Lung Cancer Screening Option for Qualified GE CT Systems
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: July 30, 2015
Received: July 31, 2015

Dear John Jaeckle:

This letter corrects our substantially equivalent letter of August 14, 2015.

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" (21CFR 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 A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
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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)*
K151372

Device Name
Low Dose CT Lung Cancer Screening Option for Qualified GE CT Systems

Indications for Use *(Describe)*
The Low Dose CT (LDCT) Lung Cancer Screening Option (LCS) for Qualified GE Systems is indicated for using low dose CT for lung cancer screening. The screening must be performed within the established inclusion criteria of programs/ protocols that have been approved and published by either a governmental body or professional medical society.

*Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Section 5: 510(k) Summary

Low Dose CT Lung Cancer Screening Option for Qualified GE CT Systems

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Date: May 19, 2015

Submitter:
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PRODUCT IDENTIFICATION

Device Trade Name: Low Dose CT Lung Cancer Screening Option for Qualified GE CT Systems

Common/Usual Name: Low Dose CT Lung Cancer Screening Option for Qualified GE CT Systems

Classification Name: Computed Tomography X-ray System or accessory per 21CFR892.1750

Product Code: 90-JAK

Manufacturer / Design Location:
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Manufacturing Location(s):
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Marketed Devices:

GE Healthcare is seeking a Low Dose CT Lung Cancer Screening (LDCT LCS) Indication for Use for both current production and installed base CT systems that meet certain important criteria/specifications derived from the review of existing chest CT reference protocols already incorporated on GE CT systems, and from various current clinical sources including published clinical trials, Medical Professional Societies, and governmental review bodies. The LDCT LCS Indications for Use of these "qualified" systems will be constrained to be used only within the established inclusion criteria and the screening protocols of LDCT LCS programs/protocols that have been approved and published by either a governmental body or professional medical society.

Predicate Devices:

GE LightSpeed 16 (aka LightSpeed 4.0) K013561
Product Code: JAK; Regulation Number: 892.1750

GE LightSpeed VCT (aka LightSpeed 7.0) K040372
Product Code: JAK; Regulation Number: 892.1750

DEVICE DESCRIPTION

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

Because none of the CTs will require hardware or software modifications the subject device for qualified systems in the installed base consists of:

1) a set of three reference LDCT LCS protocols (small, average, large patient) for each qualified CT System on a per CT platform basis;

2) detailed instructions on how to transfer the protocols onto the corresponding CT System; and

3) a dedicated for user's manual for LDCT LCS that covers all qualified systems.

For qualified forward production systems, the three above elements that constitute the subject device for the qualified systems in the installed will be deployed in a modified manner:

1) the 3 LDCT LCS reference protocols for the Qualified system will be loaded onto the system at the factory;

2) because the reference LDCT LCS protocols will already be on the system, there will be no need for detailed instructions on how to manually enter the protocols; and

3) the dedicated user manual for LDCT LCS may be folded in as a new separate chapter of the system's user manual.

For qualified forward production systems, the LDCT LCS "device" will be structured into the qualified systems. This will result in all qualified forward production systems always incorporating this LDCT LCS Option.

Currently the qualified systems are as follows.

16 slice Platforms/Systems

LightSpeed 16
BrightSpeed Elite
LightSpeed ^{Pro16}
Optima CT540

Wide Bore Platforms/Systems

LightSpeed RT^{16}
LightSpeed Xtra
Discovery CT590 RT
Optima CT580
Optima CT580 W
Optima CT580 RT

VCT/Optima CT660 Platforms/Systems

LightSpeed VCT
LightSpeed VCT XT
LightSpeed VCT XTe
LightSpeed ^{Pro32}
LightSpeed VCT Select
Optima CT660
Revolution EVO

HD Platforms/Systems

Discovery CT750 HD
    Discovery CT750 HD with VEO
Revolution Discovery CT
    Revolution GSI
    Revolution HD

Revolution CT (256 row)

Revolution CT

The qualified systems also include PET/CT and SPECT/CT systems that use the identified CT system.

Indications for Use:

The Low Dose CT (LDCT) Lung Cancer Screening Option (LCS) for Qualified GE Systems is indicated for using low dose CT for lung cancer screening. The screening must be performed within the established inclusion criteria of programs/ protocols that have been approved and published by either a governmental body or professional medical society.

**Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.*

Technology:

The LDCT LCS Option consists of new LDCT LCS protocols for qualified CT systems. There is nothing new with the structure of these protocols or in their operation. All qualified CT systems are currently able to execute these protocols without any need for device modification.

The LDCT LCS option consists of 3 new LDCT LCS protocols (Small, Average, Large patient) for each qualified system along with a new LCS-specific user manual.

The GE CT systems designed and cleared after the ones used in NLST (predicate devices LightSpeed 16 and LightSpeed VCT) have incremental design changes to improve performance such as thinner slices, more slices obtained per rotation, faster rotation speed, larger z-coverage, updated tubes, new dose reduction features including iterative reconstruction, higher performance DAS and detectors, and added features from NEMA XR25, and new editions of IEC 60601-2-44 to enhance safety and performance. These changes are evolutionary and do not change the basic operating principles of the CT. These changes also did not raise new questions of safety or effectiveness that were not completely addressed during their clearance process.

Adverse Effects on Health:

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

A new screening indication will, in general, raise some questions of new risks that may not be normally associated with the general use of the device.

However, chest CT's have been used to detect a variety of abnormalities that manifest themselves as density (i.e. contrast) differences, including lung nodules for close to 30 years.

For well over a decade CT has been recognized and used as the gold standard for lung nodule detection and sizing. This is due to CT's spatial resolution, geometric accuracy, and ability to create various reformats and 3D views. The high contrast environment in the chest between the lungs and the nodules makes for a relatively easy detection task for clinicians using CT images. The imaging tasks for using CT for Lung Cancer Screening as opposed to the use of CT when nodules are suspected are identical. No new technology is needed, although the advances in CT technology have allowed these scans to be effectively performed at lower doses, higher resolutions, and faster scan times.

The risks associated with a CT LCS program/protocol identified by the USPSTF are: false-negative and false-positive results; incidental findings; over-diagnosis; and radiation exposure. These risks are fundamentally the same as those associated with the use of CT when there is a suspicion that a nodule may be present. However the magnitude of the risks may be affected.

There has been much analysis in the literature about the risk vs. benefits of CT LCS for high risk populations using an established inclusion criterial and a LCS program protocol. The benefits have been demonstrated to outweigh the risks provided the

screening is performed according to established inclusion criteria (e.g. for high risk populations) and in accordance with an established CT LCS program protocol. The published literature, clinical trials, and governmental review as well as multiple medical professional society endorsements have now come to the conclusion that LDCT LCS performed under the above identified criteria is both safe and effective and provides a public health benefit to the high risk groups identified in the inclusion criteria.

The specific use (lung cancer screening for LDCT) does not impact public health to a significantly greater degree than the general use of LDCTs. The current use of CT provides significant public health benefit. Use for LDCT LCS only serves to increase the public health benefits. Large clinical trials such as NLST and I-ELCAP demonstrate that there is a significant public health benefit for using LDCT LCS for the identified high risk populations using an established LCS program protocol.

By constraining the LCS indication for use in only those already medically established LCS programs ensures that the public health impact is only positive because the screening use is only for the targeted high risk groups medically and scientifically identified, with no impact on the general population.

GE believes that there is more than sufficient scientific and medical evidence in the published literature and coverage decisions of the safety and effectiveness of LDCT LCS when performed with a pre-defined high risk group, according to a pre-defined screening program that includes dose targets.

The qualified CT systems that include the lung cancer screening option continue to comply with the applicable US and international safety and performance standards such as Code of Federal Regulations Title 21, Subchapter J – Radiological Health, NEMA, DICOM, and IEC standards.

The device is designed and manufactured under the Quality System Regulations of 21CFR 820.

Determination of Substantial Equivalence:

GE followed the November 1998 General vs. Specific Guidance document to help establish that the more specific LCS indication for use does not constitute a new intended use for the CT, and hence the Option can be further evaluated for substantial equivalence. This evaluation followed the flowchart found in the July 2014 “Evaluating Substantial Equivalence in Premarket Notifications” guidance.

Determination of substantial equivalence of the new LDCT LCS option to the predicate devices was further evaluated on the bench. The new LDCT LCS protocols for GE CT systems were tested and validated by using traditional IQ metrics on standard IQ phantoms and compared to the IQ results from systems used in the NSLT using their

respective NLST protocols. Testing was also performed using an anthropomorphic clinical simulation lung phantom where the CNR and nodule sizing were performed for Qualified CT systems using their new LDCT LCS protocols.

Below are the image quality metrics used for evaluation to determine substantial equivalence. Each metric is provided with a description of the impact/relevance of the metric for 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.
Modulation Transfer Function (MTF)	MTF is a measure of the high contrast spatial resolution performance of the system. Nodules in the lung are high contrast objects and therefore, MTF should be preserved at lower dose conditions.
Visual Resolution/Image Artifacts	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.
Noise Power Spectrum (NPS)	Similar to standard deviation of noise, changes in noise texture may result in nodule detection becoming more challenging especially if there is a significant shift in the frequency of the noise, and/or an increase in amplitude of the NPS plot.
Slice Thickness	The ability to produce slice thicknesses (FWHM of the slice sensitivity profile) that are close to the nominal slice thickness is important in defining clear edges and boundaries of the nodule and in nodule sizing.
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.

The qualified CT systems were grouped into the five platforms/families identified above in the listing of currently qualified systems. The groupings were based on image chain hardware commonalities and system capabilities. For the substantial equivalence evaluations a representative system was chosen from each family. The representative systems were: LightSpeed 16, Discovery CT590 RT, LightSpeed VCT and Optima CT 660, Discovery CT750 HD, and Revolution CT.

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 GE's published specifications for these image quality metrics, where it was found that they were substantially equivalent, as would be expected given that all qualified systems' predicate histories trace back to LightSpeed 16. Additionally, comparisons of CNR and nodule size measurements for the qualified systems using the new LDCT LCS protocols with the anthropomorphic chest phantom showed by CNR and visual assessment that the level of conspicuity of the nodules was maintained and by the measurement results that accurate sizing was also maintained.

Because GEHC does not have formal, published system level specifications for NPS and CNR, these metrics were evaluated specifically for demonstration of substantial equivalence as follows:

The CNR measurements were performed on the 5mm solid and nonsolid nodules in the lung phantom. The 5 mm nodules were the smallest available with this phantom. ROI's were placed on each nodule and one ROI was placed in the lung background and used to determine the CNR. The CNR's were then compared between the representative systems with the new GE protocols and the NLST systems with their protocols.

To ensure the measured CNRs produced excellent nodule detectability, an image with the lowest CNR from each representative system was evaluated for detectability/conspicuity of the lowest density nodule by experienced imaging physicists and applications specialists. Because these were not clinical images but rather phantom images, we believe our selection of evaluators is appropriate. In all cases, the small, lowest contrast nodule was easily seen.

NPS measurements/analyses were performed in the center of the uniform section of the Catphan with and without the 30cm body ring. These measurements were performed in images that were reconstructed with traditional algorithms and iterative reconstruction (IR). As expected, IR slightly shifted the NPS profile towards lower frequency without compromising nodule detection.

Summary of Clinical Testing

GE believes that there is more than sufficient evidence in the published literature and coverage decisions of the safety and effectiveness of LDCT LCS when performed on a pre-defined high risk group, according to a pre-defined screening program that includes dose targets. Reference publications, clinical trials, medical professional society guides and recommendations, and governmental body review and recommendations form the clinical evidence that establishes the requisite safety and effectiveness. The I-ELCAP trail published in the 2006 New England Journal of Medicine evaluated ~ 31,000 patients using a CT lung cancer screening protocol. Additionally, in the NLST ~57% of all 26,000+ CT exams were performed on GE CTs.

The I-ELCAP trial found as its principle finding that more than 80% of persons given a diagnosis of lung cancer as a result of annual CT screening had clinical stage I cancer. It also concluded that annual spiral CT screening can detect lung cancer that is curable. The NLST demonstrated that LDCT LCS in pre-determined high risk populations has a net benefit, i.e. 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. As such, GE believes that additional clinical data for our "Low Dose CT Lung Cancer Screening Option for Qualified GE CT Systems" is not needed and that comparative phantom analysis using both standard IQ phantoms and an already established anthropomorphic clinical simulation lung phantom is sufficient to demonstrate substantial equivalence**.**

Summary of Non-Clinical Testing

GE's approach to qualifying a system to be eligible to receive the "Lung Cancer Screening Option for Qualified GE CT Systems" was to: review existing reference protocols for Chest CT on GE CT systems; perform a literature review of current guidance on the appropriate CT acquisition parameters, reconstructions, and system functional performance capabilities for use in LDCT LCS. GE synthesized this information and guidance recommendations to determine acquisition and recon attributes. These attributes were used to identify GE systems that were able to meet all of them and become Qualified.

The attributes were then used, along with GE CT system knowledge, and with the guidance documents to develop LDCT LCS Scan Parameters for each CT system to be qualified.

The new GE LDCT LCS Protocols were used for testing as described in the above "Determination of Substantial Equivalence" section to qualify the CT system and the associated protocols.

Using the clinical simulated phantom, the bench test measurement results showed more than sufficient CNR for detecting and sizing of 5 mm or greater solid and nonsolid lung nodules in the small, average, and larger patients.

Substantial Equivalence Conclusion:

The Qualified CT systems that include the lung cancer screening option continue to comply with the applicable US and international safety and performance standards such as Code of Federal Regulations Tile 21, Subchapter J – Radiological Health, NEMA, DICOM, and IEC standards.

In order to make a Substantial Equivalence determination the new device must have the same intended use as the predicate device and the same technological characteristics or different technological characteristics that do not raise different questions of safety and effectiveness than the predicate device. In the opinion of GE Medical Systems, this has been demonstrated following the "General vs. Specific" and "Evaluating Substantial Equivalence in Premarket Notifications" guidance documents and the successful results of the bench testing.

The addition of the Low Dose CT Lung Cancer Screening Option for Qualified GE Systems when applied to the existing qualified systems results in the combination being of comparable type and substantially equivalent to the currently marketed predicate systems LightSpeed 16 (K013561) and LightSpeed VCT (K040372).