510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 24, 2010
Submitter:	GE Healthcare, (GE Medical Systems LLC) 3000 Grandview Blvd Waukesha Wisconsin 53188
Primary Contact Person:	Stephen G. Slavens, RAC Global Regulatory Affairs Director GE Healthcare, (GE Medical Systems LLC) TEL: (262) 548-4992 FAX: (262) 548-3884
Secondary Contact Person:	Helen Peng Regulatory Affairs Leader GE Healthcare, (GE Medical Systems LLC) TEL: (262) 548-5091 FAX: (262) 548-3884
Device Trade Name:	THORACIC VCAR
Device Common Name:	THORACIC VCAR
Classification Names: Product Code:	21CFR 892.2050 Picture archiving and communications system 90LLZ
Predicate Device(s):	K083227: Vida Pulmonary Workstation 2 K071513: Syngo InSpace 4D
Device Description:	Thoracic VCAR is a CT post-processing software for the GE Advantage Workstation (AW) platform. It is designed for the analysis and processing of volumetric CT chest data. It provides quantitative information to aid in the assessment of respiratory diseases. The primary features of the software are: lung and lobe segmentation to obtain threshold based volume measurements; bronchial tree segmentation and tracking to determine wall thickness measurements; lung maps based on HU values to help the physician in determining the location and extent of disease across both lungs as well as each lobe.

Intended Use:	Thoracic VCAR is a CT, non-invasive image analysis software package, which may be used in conjunction with CT lung images to aid in the assessment of thoracic disease diagnosis and management. The software will provide automatic segmentation of the lungs and automatic segmentation and tracking of the airway tree. The software will provide quantification of Hounsfield units and display by color the thresholds within a segmented region.
Technology:	THORACIC VCAR provides same type of images and results as its predicate devices. Main features include: • lung and lobe segmentation • lung and lobe volume measurements • bronchial tree segmentation and tracking • bronchial wall thickness measurements • lung maps based on HU values The THORACIC VCAR employs the same fundamental scientific technology as its predicate devices.
Determination of Substantial Equivalence:	Summary of Non-Clinical Tests: THORACIC VCAR complies with DICOM Standard NEMA PS 3.1 - 3.18(2008). The following quality assurance measures were applied to the development of the system: • Risk Analysis • Requirements Reviews • Design Reviews • Performance testing (Verification) • Safety testing (Verification) • Final acceptance testing (Validation) Summary of Clinical Tests: The subject of this premarket submission, THORACIC VCAR, did not require clinical studies to support substantial equivalence.
Conclusion:	GE Healthcare considers THORACIC VCAR to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Stephen Slavens
Regulatory Affairs Director, MI & CT
GE Medical Systems, LLC
3000 N. Grandview Blvd.
WAUKESHA WI 53188

MAR - 7 2011

Re: K103480
Trade/Device Name: THORACIC VCAR
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 21, 2011
Received: February 24, 2011

Dear Mr. Slavens:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103480

Device Name: THORACIC VCAR

Indications for Use:

Thoracic VCAR is a CT, non-invasive image analysis software package, which may be used in conjunction with CT lung images to aid in the assessment of thoracic disease diagnosis and management. The software will provide automatic segmentation of the lungs and automatic segmentation and tracking of the airway tree.
The software will provide quantification of Hounsfield units and display by color the thresholds within a segmented region.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K103480