K113408

GE Healthcare

FEB 2 4 2012

510(k) Summary of Safety and Effectiveness (in accordance to 21 CFR 807.87(h))

Device Name

Proprietary Device Name:	Q.freeze Software
Date prepared:	November 18, 2011

Establishment Name and Registration Number of Submitter

Name:	GE Medical Systems LLC
Registration Number:	2126677
Corresponding Official:	D. Duersteler GE Healthcare P.O. Box 414 Milwaukee, WI 53201 Phone: 262-312-7029 FAX: 262-312-7144 Email: david.duersteler@med.ge.com

Device Classification

Classification Code:	90 KPS
Panel Identification:	Radiology
Classification Name:	Emission Computed Tomography System (Per 21CFR 892.1200)
Common Name:	PET/CT Imaging Software
Classification Class:	Class II Product
Reason for 510(k) Submission:	New device

Device Description

Motion VUE2 (Q.freeze) is a modification to the existing Motion VUE application. Motion VUE is a software application that provides review tools necessary for viewing, staging, planning and monitoring disease in respiratory gated PET and CT data sets. It is intended for use on Advantage Workstation platforms.

Motion VUE2 (Q.freeze) is product delivers the Non-Rigid Registration (NRR) function (Motion Freeze function) to the existing Motion VUE application on AW. The Motion VUE 2 program delivers:

1. Non-Rigid Registration of PET Gated Images
2. Visualization of Registered PET Gated Images
3. Visualization of Registered Average PET Gated Images
4. Presentation Layouts to display the Registered and Registered Average PET Images

(Non-rigid registration includes spatial normalization, which may be used to transform a patient data set to match a standardized anatomical space).

Identification of Legally Marketed Equivalent Devices

Discovery PET/CT 600 and 690	GE Medical Systems LLC	K081496

Comparison with Predicate Devices

MotionVUE2 (Q.freeze) PET Software is similar in design, materials, energy sources, and technology to the above predicate devices. All major features have been previously marketed, and intended uses are substantively the same. Q.Freeze performs as well as currently marketed devices, introduces no significant change in safety or effectiveness as compared to the predicate devices, and is therefore substantially equivalent in terms of safety and effectiveness to the currently marketed MotionVue on GE Healthcare's Discovery Series of products.

Indications for Use of Device

MotionVUE2 (Q.freeze) is a PET/CT, non-invasive image analysis software application designed to support the viewing and manipulation of medical images from PET and CT imaging modalities.
MotionVUE2 (Q.freeze) offers processing tools to optimize workflow of respiratory gated exams for PET, CT and fused images of respiratory gated datasets for simultaneous viewing in multi-planar volumes and cine loops.
MotionVUE2 (Q.freeze) allows the users to generate from their 4D-PET or 4D-PET/CT series a registered 4D-PET series used for quantification of lesions and analysis of functional activity.
With MotionVUE2 (Q.freeze), users will have the possibility to compare static PET/CT, 4D-PET/CT, and registered 4DPET series including visual comparison, quantification of lesions, and analysis of functional activity.
MotionVUE2 (Q.freeze) provides registration performance of up to 2 mm of center of mass motion when motion is no larger than the diameter of the object.
MotionVUE2 (Q.freeze) provides comparable/equivalent improvement of quantification results (SUV and size) as 4D PET techniques.
MotionVUE2 (Q.freeze) can be used for features with locally concentrated activity within the entire Thorax area. This area includes the organs where PET/CT imaging has the most challenges due to respiratory motion: Lung, Liver, Pancreas.

Conclusion

In the opinion of General Electric Medical Systems, the Q.freeze Software is substantially the same in design, materials, energy sources, and technology, does not introduce new safety concerns, performs as well as currently marketed devices, and is therefore substantially equivalent in terms of safety and effectiveness to the currently marketed MotionVUE (K081496).

General Electric Company
P.O. Box 414
Milwaukee, WI 53201

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. David Duersteler
Safety and Regulatory Engineering
GE medical Systems LLC
3000 N. Grandview Blvd.
WAUKESHA WI 53188

FEB 2 4 2012

Re: K113408
Trade/Device Name: GE Q.Freeze software
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: November 18, 2011
Received: November 28, 2011

Dear Mr. Duersteler:

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.

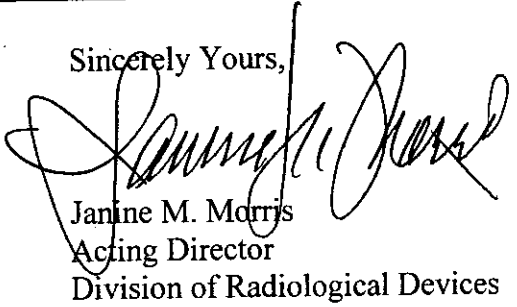
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



Janine M. Morris
Acting 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): K113408

Device Name: GE Q.Freeze software

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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 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 for Janine Morris
(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K113408