JAN - 6 2010

510(k) Summary

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

Date: 09/18/2009

Submitter: GE Healthcare, (GE Medical Systems, LLC)
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Device: Trade Name: 3DASL

Common/Usual Name: 3D ASL

Classification Names: 21 CFR 892.1000

Product Code: 90-LNH

Predicate Device(s): K083147, Discovery MR450 (GE Medical Systems, LLC)
K072237, MAGNETOM Verio (Siemens AG)

Device Description: Arterial Spin Labeling (ASL) is an MR technique using the water in arterial blood as an endogenous tracer to evaluate perfusion non-invasively. It provides a non-contrast way to visualize brain perfusion and functional physiology by allowing quantitative cerebral blood flow (CBF) measurements.

GE 3D ASL is an integration of a novel pulsed-continuous labeling technique and a 3D fast spin echo (FSE) acquisition.

The application involves performing inversion of the spins using multiple RF pulses (based on the theory of adiabatic inversion) to label the artery blood spins for the first labeling image. The second image acquisition (also known as control) is performed without inversion of the blood spins. The subtraction of the labeling and control images gives perfusion-weighted images. Additional acquisition of proton density weighted images is then used in combination with the difference images to compute quantitative cerebral blood flow.

The pulsed continuous labeling allows for high labeling efficiency leading to high SNR perfusion images while the 3D FSE readout allows for whole brain coverage and robustness to susceptibility artifacts. The high labeling efficiency is in part due to significantly reduced Magnetization Transfer (MT) effects. The short RF pulses also lead to a significant decrease in the duty cycle when compared to continuous labeling. In addition background suppression is used to reduce the sensitivity of 3D ASL to motion artifacts.

Intended Use: 3D ASL is a software option intended for use on GE 1.5T and 3.0T MR systems. It is indicated for magnetic resonance imaging of the brain.

3D ASL allows for generation of maps representing blood flow without the use of an exogenous contrast agent. 3D ASL utilizes water in arterial blood as an endogenous contrast media, to visualize tissue perfusion and evaluate cerebral blood flow (CBF).

When interpreted by a trained physician, images generated by 3D ASL provide information that can be useful in determining a diagnosis.

Technology: 3D ASL uses pulsed continuous labeling method to achieve the effects of continuous labeling. A train of very short RF pulses is used to obtain inversion (label) of blood spins. The amplitude and phase of the RF pulses are adjusted to achieve the labeling. In addition multiple selective and non-selective inversion pulses are employed to obtain static tissue suppression (aka background suppression). This allows for limited motion insensitivity as well as higher dynamic range for the perfusion images. 3DFSE with spiral readout is used for acquisition, combining the robustness of 3DFSE method and inherent oversampling nature of spiral trajectory. 3D ASL employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Testing:

The 3D ASL application complies with voluntary standards as detailed in Section 9 of this premarket submission. The following quality assurance measures were applied to the development of the application:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Design Verification
- Design Validation

The following safety parameters have been measured:

- Acoustic noise
- dB/dt
- SAR

The following performance parameters have been measured:

- Reproducibility
- Repeatability
- Signal-to-noise ratio (SNR)

The following clinical testing has been performed to validate the 3D ASL technique:

- Clinical evaluation
- Volunteer imaging

Conclusion: GE Healthcare considers the 3D ASL to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

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. Yuan Ma
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Re: K092925
Trade/Device Name: 3D ASL
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: December 11, 2009
Received: December 14, 2009

Dear Mr. Ma:

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 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K092925

Device Name: 3D ASL

Indications for Use:

3D ASL is a software option intended for use on GE 1.5T and 3.0T MR systems. It is indicated for magnetic resonance imaging of the brain.

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When interpreted by a trained physician, images generated by 3D ASL provide information that can be useful in determining a diagnosis.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092925