MAR 2 2 2011

GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

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

Date: March 21, 2011

Submitter: GE Healthcare (GE Medical Systems, LLC)
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USA

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Device: Trade Name: IDEAL IQ Software Option

Common/Usual Name: Software Option for Magnetic Resonance Imaging System

Classification Names: 21 C.F.R. 892.1000
Magnetic Resonance Diagnostic Device

Product Code: LNH

Predicate Device(s): IDEAL Software Option, K072998

Device Description: IDEAL IQ is a software application offered as an option for GE MR scanners. The IDEAL IQ imaging technique (IDEAL: Iterative Decomposition of water and fat with Echo Asymmetry and Least-squares estimation) is a triglyceride fat and water separation technique that acquires multiple images of the anatomy at separate echo times to calculate the phase differences and determine triglyceride fat and water content per pixel. It exploits the resonance frequency differences between triglyceride fat and water, measured as phase differences in multiple echoes, to resolve triglyceride fat and water. It provides reliable and

uniform water-fat separation in the presence of B0 field inhomogeneity and improves the accuracy of water-fat separation by estimating and correcting for T2* decay between echoes and by more accurately modeling triglyceride fat's spectral profile as multiple peaks rather than a single peak. It produces images showing the separated water and triglyceride fat signals, and the tissue transverse magnetization relaxation. Finally, IDEAL IQ processes decomposed water and triglyceride fat images to generate a relative triglyceride fat-fraction map. Such a representation of a proton density triglyceride fat fraction is intrinsically insensitive to B1 and coil-sensitivity heterogeneity. The IDEAL IQ method uses a low flip angle excitation to reduce any T1 bias in the relative triglyceride fat fraction map images caused by differences in the T1 of triglyceride fat and water. With the confounding effects of T2*, multiple spectral peaks of triglyceride fat, and T1 differences reduced, the images from IDEAL IQ reflect the spatial distribution of relative concentration of triglyceride fat in a voxel.

Intended Use: IDEAL IQ is a software option intended for use on GE MR systems. IDEAL IQ is capable of producing transverse, sagittal, coronal, and oblique images of internal structures of the body, including but not limited to, the musculoskeletal, breast, abdominal, and neurological systems. Specific anatomical regions that may be imaged include the abdomen, breast, spine, joints, and extremities.

IDEAL IQ is an acquisition and reconstruction technique that simultaneously obtains independent images of hydrogen nuclei that resonate at different frequencies to provide separation of water and triglyceride fat. IDEAL IQ generates images of separated water and triglyceride fat, relative triglyceride fat fraction map, and tissue transverse magnetization relaxation. In the liver, the relative triglyceride fat fraction map is quantitative; it reflects the proton density (number of protons per unit volume) of triglyceride fat, divided by the sum of the proton density of triglyceride fat and the proton density of water, on a voxel-by-voxel basis.

When interpreted by a trained physician, these images provide information that can aid in diagnosis.

Technology: The IDEAL IQ acquisition uses a fast 3D SPGR sequence in one or more repetitions. IDEAL IQ exploits the resonant frequency difference between triglyceride fat and water, measured as phase differences in multiple echoes. The IDEAL IQ software option employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The IDEAL IQ software option complies with voluntary standards as detailed in Section 9, 11, 16 and 18 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Design Verification
- Safety Testing

The following safety parameters were measured:

- Acoustic Noise
- dB/dt
- SAR

The non-clinical tests outlined above have been executed with acceptable results. Refer to Sections 9, 16, and 18 of this submission for testing results.

Summary of Clinical Tests:

Clinical image comparisons demonstrate that the IDEAL IQ software option maintains the same imaging performance results as the predicate software option IDEAL. Quantification in the liver is shown through included studies of animal models, and several in vivo human studies showing correlation to MR Spectroscopy.

Conclusion: GE Healthcare considers the IDEAL IQ software option to be as safe, as effective, and performance is substantially equivalent to the predicate device.

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

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MAR 2 2 2011

Re: K103411
Trade/Device Name: IDEAL IQ Software Option
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: II
Product Code: LNH
Dated: February 23, 2011
Received: February 24, 2011

Dear Ms. Fox,

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 S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K103411
Device Name: IDEAL IQ Software Option

Indications for Use
IDEAL IQ is a software option intended for use on GE MR systems. IDEAL IQ is capable of producing transverse, sagittal, coronal, and oblique images of internal structures of the body, including but not limited to, the musculoskeletal, breast, abdominal, and neurological systems. Specific anatomical regions that may be imaged include the abdomen, breast, spine, joints, and extremities.

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When interpreted by a trained physician, these images provide information that can aid in 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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k)_____