K122035
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Resonance Health

DEC 13 2013

510(k) Summary

DATE:	October 30th, 2013
SUBMITTED BY:	Resonance Health Analysis Services Pty Ltd 278 Stirling Highway Claremont WA 6010 Australia
Contact in Australia:	Mr Andrew Bathgate Quality Assurance and Regulatory Affairs Manager Tel: +61 8 9286 5300 Fax: +61 8 9286 1179
Contact in the US:	Mr Greg Holland Regulatory Specialists Inc. 3722 Ave. Sausalito Irvine, CA 92606 Tel: 949-262-0411 Fax: 949 552 2821
NAME OF DEVICE:	HepaFat-Scan
CLASSIFICATION NAME:	Magnetic Resonance Diagnostic Device (21 CFR 892.1000)
PRODUCT CODE:	90 LNH
TRADE NAME:	HepaFat-Scan
PREDICATE DEVICE(S):	K103411: IDEAL IQ Software Option K043271: R2-MRI Analysis System
DEVICE DESCRIPTION:	Standalone software application to facilitate the import and visualization of multi-slice, gradient-echo MRI data sets encompassing the abdomen, with functionality independent of the MRI equipment, to provide objective and reproducible determination of the triglyceride fat fraction in magnetic resonance images of the liver. It utilises magnetic resonance images that exploit the difference in resonance frequencies between hydrogen nuclei in water and triglyceride fat. The quantitative triglyceride fat fraction is based on the measurement of a magnetic resonance parameter that reflects the ratio of the proton density signal of triglyceride fat to the total proton density signal in the liver.

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INTENDED USE: HepaFat-Scan is a software device intended for quantitative measurement of the triglyceride fat fraction in magnetic resonance images of the liver. It utilises magnetic resonance images that exploit the difference in resonance frequencies between hydrogen nuclei in water and triglyceride fat. The quantitative triglyceride fat fraction is based on the measurement of a magnetic resonance parameter that reflects the ratio of the proton density signal of triglyceride fat to the total proton density signal in the liver.

When interpreted by a trained physician, the results provide information that can aid in diagnosis.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The device has been shown to be substantially equivalent to the R2-MRI Analysis System (K043271) and the IDEAL IQ Software Option (K103411). Technological similarities between HepaFat-Scan and the two predicates include:

- Similar Intended Uses in that the devices utilize MR images to make quantitative measurements of a physiological characteristic of the liver.
- Similar Intended Purposes in that the devices are used to support clinical diagnoses.
- Devices are stand-alone software applications, independent from the MR scanner.
- Devices utilize multi-echo and multi slice images.
- Devices facilitate the import, visualization and analysis of MR images.

In addition, HepaFat-Scan has the following specific technological similarities with the Ideal IQ Software device (K103411):

- Both devices utilize the resonance frequency differences between water and fat protons in the fat measurements.
- Both devices incorporate techniques to take into account the effects of T2* on the fat measurement.
- Both devices provide a fat fraction measurement.

Accuracy and reproducibility of the quantification of the triglyceride fat fraction has been demonstrated through a combination of bench testing and in-vivo human clinical studies. A phantom was utilized to demonstrate equivalence between different scanner models. Volumetric fat fractions were determined from liver biopsy samples for clinical comparison with HepaFat-Scan using a stereological method based on the Delesse principle, which directly measures volumetric fat fraction. Acceptable agreement was attained when comparing the liver biopsy volumetric fat fraction measurements to the HepaFat-Scan device output over a clinically wide range of liver fat fractions.

CONCLUSION

Resonance Health considers the HepaFat-Scan software device to be substantially equivalent to the predicate devices R2-MRI Analysis System (K043271) and the IDEAL IQ Software Option (K103411), in respect to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

RESONANCE HEALTH ANALYSIS SERVICES PTY LTD
% GREG HOLLAND, CONSULTANT
REGULATORY SPECIALIST, INC.
3722 AVENUE SAUSALITO
IRVINE CA 92606

December 13, 2013

Re: K122035
Trade/Device Name: Hepafat Scan
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: October 30, 2013
Received: November 04, 2013

Dear Mr. Holland:

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 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. 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,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K122035

Device Name
HepaFat-Scan

Indications for Use *(Describe)*

HepaFat-Scan is a software device intended for quantitative measurement of the triglyceride fat fraction in magnetic resonance images of the liver. It utilises magnetic resonance images that exploit the difference in resonance frequencies between hydrogen nuclei in water and triglyceride fat. The quantitative triglyceride fat fraction is based on the measurement of a magnetic resonance parameter that reflects the ratio of the proton density signal of triglyceride fat to the total proton density signal in the liver.

When interpreted by a trained physician, the results provide information that can aid in diagnosis.

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)*

Michael D. O'Hara