K132381
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APR 0 4 2014

510(k) Summary

Sponsor:	ClearMRI Solutions, Inc. W315 S3283 Harvest View Drive Waukesha WI 53189
Contact:	Mary Ann Ferguson, Project Manager ClearMRI Solutions, Inc. W315 S3283 Harvest View Drive Waukesha WI 53189 Telephone: (978)-578-1196
Date Prepared:	October 15, 2013
Subject Device:	Trade Name: ClearMRI Helios-RG8 Coil Accessory Kit Common/Usual Name: MRI Coil Accessory Kit Classification Name: Magnetic resonance diagnostic device. Regulation: 21 CFR §892.1000; Classification: II; Product Code: LNH
Predicate Devices:	General Electric Signa Horizon Cx Magnetic Resonance System (K962061)

Device Description:
The ClearMRI Solutions, Inc. Helios-RG8 Coil Accessory Kit is designed as an accessory to a previously cleared GE Signa Horizon Cx MR (K962061), software build 9.1.0311b, receiver subsystem with the main modification allowing the operator to use newer RF receive coils with up to 8 channels. The accessory includes a digital receiver, multi-coil driver, and a computer system containing the ClearMRI software and functions in a similar way to the predicate device's comparable subsystem. The ClearMRI hardware is seamlessly background-driven from the GE Signa Horizon Cx system.

Intended Use:
The intended use of the ClearMRI Helios-RG8 Coil Accessory Kit is to enable the GE Signa Horizon Cx MR System to perform MR scans of the head or body utilizing newer FDA-cleared coils (up to 8 channels), without hindering its current capability utilizing the legacy GE FDA-cleared 4-channel coils. The ClearMRI Helios-RG8 Coil Accessory Kit inherits the same limitations of the GE Signa Horizon Cx MR system. The ClearMRI Helios-RG8 Coil Accessory Kit has only been validated for and is for use strictly with the GE Signa Horizon Cx MR System, software build 9.1.0311b. The ClearMRI Helios-RG8 Coil Accessory Kit allows the GE Signa Horizon Cx MR System to continue to produce transverse, sagittal, coronal and oblique images of the internal structures of the head or body with the GE Signa Horizon Cx MR System. The images produced reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. The NMR properties that determine the image appearance are proton density, spin lattice relaxation time (T1), spin-spin relaxation time (T2) and flow. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

510(k) Summary

The Helios-RG8 Coil Accessory Kit will support coil anatomies from Resonance Innovations, LLC: Long Bone Array in large (model 168GE1501).

Accessories to medical devices are regulated under the same classification regulation as the device(s) with which they are intended to be used. The ClearMRI Helios-RG8 Coil Accessory Kit is intended to be used strictly as an accessory to the GE Signa Horizon Cx MR System, software build 9.1.0311b, and does not change the existing indications for the GE Signa Horizon Cx MR System (K962061).

Technological Characteristics:
The ClearMRI Solutions Helios-RG8 Coil Accessory Kit includes a digital receiver, multi-coil driver and a computer system containing the ClearMRI software. The accessory kit is available as an add-on to a GE Signa Horizon Cx MR, software build 9.1.0311b, receiver subsystem that allows the operator to scan using a digital imaging system resulting in the benefits of newer multi-channel RF coils. The ClearMRI hardware is controlled by software running independently and in parallel with the GE Signa Horizon Cx System. It does not alter the existing operator workflow. The Helios-RG8 has no new technological characteristics that raise new safety or effectiveness questions.

Performance Data:
The ClearMRI Helios-RG8 device will support up to eight channel coils. The accessory kit was evaluated to the appropriate NEMA standards and IEC 60601 medical device safety standards as well as IEC 60601-1-2 EMI/EMC standards.

Substantial Equivalence:
The ClearMRI Solutions, Inc. (CMS) Helios-RG8 Coil Accessory Kit is designed as an add-on accessory to a GE Signa Horizon Cx MR, software build 9.1.0311b, receiver subsystem that allows the operator the use of newer RF coils (up to 8-channels). Accessories to medical devices are regulated under the same classification regulation as the device(s) with which they are intended to be used. The accessory kit does not significantly affect the performance of the legally marketed GE Signa Horizon Cx System, software build 9.1.0311b, and is therefore substantially equivalent. Nonclinical test data demonstrate that the device is safe and effective and is substantially equivalent to the legally marketed predicate device.

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

April 4, 2014

ClearMRI Solutions, Inc.
% Mr. Mark Job
Responsible Third Party Official
1394 25th Street NW
BUFFALO MN 55313

Re: K132381
Trade/Device Name: ClearMRI Helios-RG8 Coil Accessory Kit
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: March 20, 2014
Received: March 21, 2014

Dear Mr. Job:

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

Indications for Use

Indications for Use

510(k) Number: K132381

Device Name:
ClearMRI Helios-RG8 Coil Accessory Kit

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K132381