K110120

Submitter Information

FEB 25 2011

Submitter:	Hitachi Medical Systems America, Inc. 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371 TEL: (330) 425-1313 FAX: (330) 963-0749
Contact:	Douglas J. Thistlethwaite
Date:	January 14, 2011

Device Name

Classification Name:	Coil, magnetic resonance, specialty
Classification Number:	90MOS
Trade/Proprietary Name:	ECHELON Rapid Cardiac Coil
Predicate Device:	MR-RCC-150 Cardiac Coil (K063513)

Device Intended Use

The ECHELON Rapid Cardiac Coil is a receive-only, multiple array coil used for magnetic resonance imaging of the musculoskeletal structures, soft tissue and vascular structures of various anatomic regions. It is designed to be used the Hitachi ECHELON 1.5T MRI system.

Device Description

Function

The ECHELON Rapid Cardiac Coil is a receive only RF phased array coil, used for obtaining diagnostic images of the cardiac region, in an open Magnetic Resonance Imaging (MRI) system.

Scientific Concepts

Magnetic Resonance Imaging (MRI) is based on the fact that certain atomic nuclei have electromagnetic properties that cause them to act as small spinning bar magnets. The most ubiquitous of these nuclei is hydrogen, which makes it the primary nuclei currently used in magnetic resonance imaging. When placed in a static magnetic field, these nuclei assume a net orientation or alignment with the magnetic field, referred to as a net magnetization vector. The introduction of a short burst of radiofrequency (RF) excitation of a wavelength specific to the magnetic field strength and to the atomic nuclei under consideration can cause a re-orientation of the net magnetization vector. When the RF excitation is removed, the protons relax and return to their original vector. The rate of relaxation is exponential and varies with the character of the proton and its adjacent molecular environment. This re-orientation process is characterized by two exponential relaxation times, called T1 and T2.

A RF emission or echo that can be measured accompanies these relaxation events. The emissions are used to develop a representation of the relaxation events in a three dimensional matrix. Spatial localization is encoded into the echoes by varying the RF excitation, applying appropriate magnetic field gradients in the x, y, and z directions, and changing the direction and strength of these gradients. Images depicting the spatial distribution of the NMR characteristics can be reconstructed by using image processing techniques similar to those used in computed tomography.

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Physical and Performance Characteristics

The ECHELON Rapid Cardiac Coil is a receive-only coil designed to contour to the outline of the shoulder. The coil consists of 12 elements. The signal output of each element is independently processed by the MRI system to enhance performance.

Device Technological Characteristics

The technological characteristics of the ECHELON Rapid Cardiac Coil are exactly the same to the predicate device as listed in Section 10 – Substantial Equivalence Discussion.

Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. that the ECHELON Rapid Cardiac Coil is substantially equivalent to the listed predicate device.

Contrast Agent Use

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Hitachi Medical Systems America, Inc
Contact: Doug Thistlethwaite

Feature	Predicate
The Coil Specification Document (DCA # 2-001017) contains requirements that the coil support acquisition of contrast-enhanced MRA for the heart and surrounding vasculature as well as cardiac perfusion studies. The coil does not include these protocols; a design requirement of the coil is the ability to acquire these images.	k063513 - EchelonTM MR-RCC-1 50 Cardiac Coil

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. Doug Thistlewaite
Manager of Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087

FEB 25 2011

Re: K110120
Trade/Device Name: ECHELON Rapid Cardiac Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: January 14, 2011
Received: January 18, 2011

Dear Mr. Thistlewaite:

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

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: **ECHELON Rapid Cardiac Coil**

Indications For Use:

The ECHELON Rapid Cardiac Coil is a receive-only, multiple array coil used for magnetic resonance imaging of the musculoskeletal structures, soft tissue and vascular structures of various anatomic regions. It is designed to be used the Hitachi ECHELON 1.5T MRI system.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 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 Device Evaluation (ODE)~~ OIVD

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110120