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Submitter Information

Submitter:	Hitachi Medical Corporation 2-1, Shintoyofuta Kashiwa-shi, Chiba, JAPAN 277-0804
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Contact:	Douglas J. Thistlethwaite
Date:	November 13, 2007

Device Name

Classification Name:	Coil, magnetic resonance, specialty
Classification Number:	90MOS
Trade/Proprietary Name:	OASIS CTL Coil
Predicate Device(s):	ECHELON Whole Spine (CTL) Coil
Classification Name:	Coil, magnetic resonance, specialty
Classification Number:	90MOS
Trade/Proprietary Name:	OASIS QD Flexible Body Coil (L)
Predicate Device(s):	ALTAIRE Flex Body (Large) Coil
Classification Name:	Coil, magnetic resonance, specialty
Classification Number:	90MOS
Trade/Proprietary Name:	OASIS QD Flexible Body Coil (XL)
Predicate Device(s):	ALTAIRE Flex Body (Extra Large) Coil
Classification Name:	Coil, magnetic resonance, specialty
Classification Number:	90MOS
Trade/Proprietary Name:	OASIS RAPID Foot Coil
Predicate Device(s):	OASIS RAPID Head Coil

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Device Intended Use

The MR system is an imaging device and is intended to provide the physician with physiological and clinical information, obtained non-invasively and without the use of ionizing radiation. The OASIS Specialty Coils are receive-only devices that detects the MR signal used to produce transverse, coronal, sagittal, oblique, and/or curved cross-sectional images that display the internal structure of the body. The images produced by the MR system reflect the spatial distribution of protons (hydrogen nuclei) exhibiting magnetic resonance. When interpreted by a trained physician, these images provide information that can be useful in diagnosis determination.

The indications for use for the OASIS Specialty Coils are as follows:

- The **MR-CTL-120, OASIS CTL Coil** is a recieve-only multiple array device used for MRI imaging of the human cervical spine, and thoracic spine.
- The **MR-QFC-120, OASIS QD Flexible Body Coil (L)** is a recieve-only multiple array device used for MRI imaging of the abdomen.
- The **MR-QFC-120, OASIS QD Flexible Body Coil (XL)** is a recieve-only multiple array device used for MRI imaging of the abdomen.
- The **MR-RFC-120, OASIS Rapid Foot Coil** is a recieve-only multiple array device used for MRI imaging of the foot.

Device Description

Function

The **MR-CTL-120, OASIS CTL Coil** is a recieve-only multiple array device used for obtaining diagnostic images of the human cervical spine, and thoracic spine with the OASIS MRI System.

The **MR-QFC-120, OASIS QD Flexible Body Coil (L)** is a recieve-only multiple array device used for obtaining diagnostic images of the abdomen with the OASIS MRI System.

The **MR-QFC-120, OASIS QD Flexible Body Coil (XL)** is a recieve-only multiple array device used for obtaining diagnostic images of the abdomen with the OASIS MRI System.

The **MR-RFC-120, OASIS Rapid Foot Coil** is a recieve-only multiple array device used for obtaining diagnostic images of the foot with the OASIS MRI System.

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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.

Physical and Performance Characteristics

The **MR-CTL-120, OASIS CTL Coil** is a recieve-only device suitable for imaging human cervical spine, thoracic spine, lumber spine and etc. The coil consists of 8 elements. The signal output of each element is independently processed by the MRI system to enhance performance.

The **MR-QFC-120, OASIS QD Flexible Body Coil (L)** is a recieve-only suitable for imaging the abdomen. The coil consists of 2 elements. The signal output of each element is independently processed by the MRI system to enhance performance.

The **MR-QFC-120, OASIS QD Flexible Body Coil (XL)** recieve-only suitable for imaging the abdomen. The coil consists of 2 elements. The signal output of each element is independently processed by the MRI system to enhance performance.

The **MR-RFC-120, OASIS Rapid Foot Coil** recieve-only suitable for imaging human foot region, muscle, born structure, cartilage, etc. The coil consists of 8 elements. The signal output of each element is independently processed by the MRI system to enhance performance.

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Device Technological Characteristics

The technological characteristics of the OASIS Specialty Coils are similar to the predicate devices as listed in Section 7 – Predicate Device Comparison.

Conclusions

It is the opinion of Hitachi Medical Systems America, Inc. that OASIS Specialty Coils substantially equivalent to the listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2008

Hitachi Medical Corporation
% Mr. Doug Thistlethwaite
Manager, Regulatory Affairs
Hitachi Medical System America, Inc.
1959 Summit Commerce Park
TWINSBURG OH 44087

Re: K073310
Trade/Device Name: OASIS CTL Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 19, 2007
Received: November 23, 2007

Dear Mr. Thistlethwaite:

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 such 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); 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.

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 Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K073310

Device Name: OASIS CTL Coil

Indications for Use:

The MR-CTL-120, OASIS CTL Coil is a recieve-only multiple array device used for MRI imaging of the human cervical spine, and thoracic spine.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073310

510(k) Number (if known): K073310

Device Name: OASIS QD Flexible Body Coil (L)

Indications for Use:

The MR-QFC-120, OASIS QD Flexible Body Coil (L) is a recieve-only multiple array device used for MRI imaging of the abdomen.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073310

510(k) Number (if known): K073310

Device Name: OASIS QD Flexible Body Coil (XL)

Indications for Use:

The MR-QFC-120, OASIS QD Flexible Body Coil (XL) is a recieve-only multiple array device used for MRI imaging of the abdomen.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073310

510(k) Number (if known): K073310

Device Name: OASIS Rapid Foot Coil

Indications for Use:

The MR-RFC-120, OASIS Rapid Foot Coil is a recieve-only multiple array device used for MRI imaging of the foot.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K073310