K073181
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510(k) Summary of Safety and Effectiveness

Device Name:	NeoCoil 1.5T 16-Channel Cardiac-Abdominal-Pelvic Array Coil
Proprietary Name:	NeoCoil 1.5T 16-Channel Cardiac-Abdominal-Pelvic Array Coil
Common/Usual Name:	Magnetic Resonance Specialty Coil
Classification Name:	Magnetic Resonance Specialty Coil
Classification Number:	892.1000
Classification Panel:	Radiology Device Panel
CDRH Product Code:	MOS
Regulatory Class:	II
Reason for 510(k):	New device

NOV 2 1 2007

Applicant:

Brian Brown
Executive Director
NeoCoil
N27 W23910A Paul Rd
Pewaukee, WI 53072
262-347-1250 x 12 (office)
261-347-1251 (fax)
brian.brown@neocoil.com

Preparation date:	9/28/2007
Est. Registration No:	3006369484

Intended Use: To be used in conjunction with 1.5T GE HD series Magnetic Resonance scanners to produce diagnostic images of the chest, abdominal, and pelvic regions that can be interpreted by a trained physician.

Standards:

Performance: No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.

Voluntary:

IEC 60601-1	Medical Electrical Equipment—Part 1: General Requirements for Safety
IEC 60601-2-33	Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis
NEMA MS-6	Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images

Device Description: The NeoCoil 1.5T 16-Channel Cardiac-Abdominal-Pelvic Array Coil is a multi-element phased array receive only coil used for obtaining diagnostic images of the chest, abdominal, and pelvic regions in Magnetic Resonance Imaging Systems. Compared to predicate device, the submitted device offers greater lateral coverage (60 cm v. 42 cm).

The submitted device consists of two dependent housings; an anterior and a posterior. The anterior housing consists of 11 antennas. It is rigid in the middle, below the covers, and laterally flexible to permit it to wrap about the patient. The posterior consists of 5 antennas. It is made of a hard plastic housing. A single cable connects the posterior housing to the junction box, which provides the interface with the anterior housing. The junction box provides the inter-

connection for the anterior and posterior housings, which are mutually dependant, and the GE Healthcare 1.5T Signa Excite MRI scanner.

The antennas are uniquely positioned with the appropriate overlap to cancel out mutual coupling effects from adjacent antennas. Pre-amplifier decoupling reduces any remaining coupling between the antennas.

The posterior housing is covered with a padded surface, of the same foam material as the anterior housing (flexible region). Hospital gowns, sheets, and/or patient street clothing separate the patient from direct contact with the coil and housing materials.

The flexible portion of the anterior secures, about the patient, to the posterior with the provided straps. The posterior housing nests securely in the MRI scanner patient table.

To ensure safety, each antenna is equipped with active and passive transmit decoupling circuits. Active decoupling is achieved via diodes that receive signals from the scanner to turn the coil to a high impedance state during system RF transmit. Crossed diodes are installed on each antenna acting as passive switches. These passive switches provide additional safety in case the active circuitry does not receive signal from the scanner.

Predicate Device:	IGC-Medical Advances Inc, Model 558GE-64 Torso Array Coil (K041185).
Comparison to Predicate:	It is our opinion that the NeoCoil 1.5T 16-Channel Cardiac-Abdominal-Pelvic Array Coil in this submission is substantially equivalent to the previously cleared IGC-Medical Advances Inc, Model 558GE-64 Torso Array Coil (K041185).
Summary of Studies:	In all material respects, the NeoCoil 1.5T 16-Channel Cardiac-Abdominal-Pelvic Array Coil is substantially equivalent to the referenced predicate device. SNR and image uniformity testing was performed which support the conclusion that the submitted device satisfies design objectives.
Conclusion:	The NeoCoil 1.5T 16-Channel Cardiac-Abdominal-Pelvic Array Coil is substantially equivalent to the predicate device. Use of the NeoCoil 1.5T 16-Channel Cardiac-Abdominal-Pelvic Array Coil does not result in any new potential hazards and does not alter the safety of the MRI scanner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2007

NeoCoil LLC
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K073181
Trade/Device Name: NeoCoil 1.5T 16-Channel Cardiac-Abdominal-Pelvic Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 8, 2007
Received: November 13, 2007

Dear Mr. Lehtonen:

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

Indications for Use

510(k) Number (if known): K073181

Device Name: NeoCoil 1.5T 16-Channel Cardiac-Abdominal-Pelvic Array Coil

Indications For Use:

To be used in conjunction with 1.5T GE HD series Magnetic Resonance scanners to produce diagnostic images of the chest, abdominal, and pelvic regions that can be interpreted by a trained physician.

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 K073181