K071611

510(k) Summary of Safety and Effectiveness

JUN 28 2007

Device Name:	NeoCoil 3.0T 8-Channel Shoulder Array Coil
Proprietary Name:	NeoCoil 3.0T 8-Channel Shoulder 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
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:	5/21/2007
Est. Registration No:	_____

Intended Use: To be used in conjunction with 3.0T GE HD series Magnetic Resonance scanners to produce diagnostic images of the shoulder 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 3.0T 8-Channel Shoulder Array Coil is a multi-element phased array receive only coil used for obtaining diagnostic images of the shoulder in Magnetic Resonance Imaging Systems. Compared to predicate devices, the submitted device offers easier patient setup and greater SNR due to its compatibility with 3.0T MRI scanners.
The submitted device consists of semi-flexible foam covered housing, consisting of eight antennas. The antennas are uniquely positioned with the appropriate overlap to cancel out mutual coupling effects from adjacent antennas or decoupled from an adjacent antenna using a transformer. Pre-amplifier decoupling reduces any remaining decoupling between the antennas.

The coil is held in place over the imaging area via a cross body strap. A system interface cable connects to the coil at the top of the housing. The flexible foam covered housing along with the body strap enable the proper positioning on the patient before laying down and holds the coil in place while scanning is being performed.

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 Devices:	USA Instruments Inc, Mark III Phased Array Shoulder Coil (K042009), NeoCoil 1.5T Shoulder Array Coil Model NC008 (K071311)
Comparison to Predicate:	It is our opinion that the NeoCoil 3.0T 8-Channel Shoulder Array Coil in this submission is substantially equivalent to the previously cleared USA Instruments Inc, Mark III Phased Array Shoulder Coil (K042009), and the NeoCoil 1.5T Shoulder Array Coil Model NC008 (K071311).
Summary of Studies:	In all material respects, the NeoCoil 3.0T 8-Channel Shoulder Array is substantially equivalent to the referenced predicate devices. SNR and image uniformity testing was performed which support the conclusion that the submitted device satisfies design objectives.
Conclusion:	The NeoCoil 3.0T 8-Channel Shoulder Array is substantially equivalent to the predicate device. Use of the NeoCoil 3.0T 8-Channel Shoulder Array does not result in any new potential hazards and does not alter the safety of the MRI scanner.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 28 2007

NeoCoil
% Mr. Daniel Lehtonen
Senior Staff Engineer – Medical Devices
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K071611
Trade/Device Name: NeoCoil 3.0T 8-Channel Shoulder Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: June 12, 2007
Received: June 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 (Premarket Approval), 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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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): K071611

Device Name: NeoCoil 3.0T 8-Channel Shoulder Array Coil

Indications For Use:

To be used in conjunction with 3.0T GE HD series Magnetic Resonance scanners to produce diagnostic images of the shoulder that can be interpreted by a trained physician.

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071611

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)

Page 1 of 1