K073236

510(k) Summary

Proprietary Name:	NeoCoil 3.0T 32-Channel Torso Array Coil
Common Device Name:	Magnetic Resonance Specialty Coil
Regulation Number:	892.1000
Review Panel:	Radiology Device Panel
CDRH Product Code:	MOS
Device Class:	II
Reason for 510(k):	New device
Applicant:	NeoCoil N27 W23910A Paul Rd Pewaukee, WI 53072
Contact	Brian Brown Executive Director 262-347-1250 x 12 (office) 261-347-1251 (fax) brian.brown@neocoil.com
Preparation date:	04/02/2007
Est. Registration No:	_____

NOV 3 0 2007

Intended Use:	The NeoCoil 3.0T 32-Channel Torso Array Coil is a receive only phased array RF coil used to produce diagnostic images of the chest, abdomen, and pelvic area in Magnetic Resonance Imaging systems that can be interpreted by a trained physician. The NeoCoil 3.0T 32-Channel Torso Array Coil is designed for use with the 3.0T HD Series MR System manufactured by General Electric Healthcare (GEHC).
Indications for Use	The NeoCoil 3.0T 32-Channel Torso Array Coil is intended to be used in the abdomen, pelvis, and chest regions for 2D and 3D magnetic resonance imaging and parallel body imaging for use on 3.0T GE HD series Magnetic Resonance scanners.
Performance Standards:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
Device Description:	The NeoCoil 3.0T 32-Channel Torso Array Coil is a multi-element phased array receive only coil used for obtaining diagnostic images of the chest, abdomen, and pelvic area in Magnetic Resonance Imaging Systems. The coil consists of 2 antenna arrays; a posterior and an anterior. The posterior array contains 17 elements to achieve 16 channels and is enclosed in a rigid housing. The anterior array also contains 17 elements to achieve the later 16 channels but is enclosed in a flexible housing. The coil is wrapped around the patient's torso with hook and loop straps. The NeoCoil 3.0T 32-Channel Torso Array Coil is for use with the GE 3.0T HD Series MR System (K052293)
Predicate Devices:	GE 3.0T Torso Phased Array Coil (K030495) GE 1.5T 8 Channel Torso Coil (K031209)
Comparison to Predicate:	The NeoCoil 3.0T 32-Channel Torso Array Coil is most similar to the GE 1.5T 8 Channel Torso Coil (K031209) with the main differences being the number of elements and the field strength. The NeoCoil Torso Coil uses 34

	elements compared to 12. It also operates at 3.0T like the GE 3.0T Torso Phased Array Coil (K030495) instead of 1.5T.
Summary of Studies:	Testing was performed to demonstrate to that the design of the NeoCoil 3.0T 32-Channel Torso Array Coil met predetermined acceptance criteria.
Conclusion:	It is the opinion of NeoCoil that the NeoCoil 3.0T 32-Channel Torso Array Coil is substantially equivalent to the predicate devices. Use of the NeoCoil 3.0T 32-Channel Torso 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 3 0 2007

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

Re: K073236
Trade/Device Name: NeoCoil 3.0T 32-Channel Torso Array Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 15, 2007
Received: November 16, 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): K073236

Device Name: NeoCoil 3.0T 32-Channel Torso Array Coil

Indications For Use:

The NeoCoil 3.0T 32-Channel Torso Array Coil is intended to be used in the abdomen, pelvis, and chest regions for 2D and 3D magnetic resonance imaging and parallel body imaging for use on 3.0T GE HD series Magnetic Resonance scanners.

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)

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(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K073236