K070778

510(k) Summary of Safety and Effectiveness

APR 11 2007

Device Name:	NeoCoil 3.0T 6-Channel Carotid Array Coil
Proprietary Name:	NeoCoil 3.0T 6-Channel Carotid 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:	12/12/2006
Est. Registration No:	_____
Intended Use:	The NeoCoil 3.0T 6-Channel Carotid Array Coil is a receive only phased array RF coil used to produce diagnostic images of the carotid arteries that can be interpreted by a trained physician. The coil provides coverage of the carotid arteries and associated vasculature from the sternal notch through the internal carotid arteries at the level of cervical vertebrae C1 in Magnetic Resonance Imaging systems. The NeoCoil 3.0T 6-Channel Carotid Array Coil is designed for use with the HD series (3.0Tesla) MRI scanners manufactured by General Electric Healthcare (GEHC). Anatomic Regions: Head and neck vasculature. Nuclei Excited: Hydrogen. The indications for use are the same as for standard imaging: The GE scanner is indicated for use as an NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time T1, spin-spin relaxation time T2, and (3) display the vasculature of the head and neck regions specifically the carotid arteries and associated soft tissue. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.
Standards: Performance:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
Device Description:	The NeoCoil 3.0T 6-Channel Carotid Array Coil is a multi-element phased array receive only coil used for obtaining diagnostic images of the carotid arteries and associated vasculature from the sternal notch through the internal carotid arteries at the level of cervical vertebrae C1 in Magnetic Resonance Imaging Systems. Compared to predicate devices, the submitted device offers greater SNR due to its operating field strength of 3.0T, and a larger field-of-view due to the antenna layout.

	The submitted device consists of a dual set of foam covered "paddles", consisting of three antennas each. The three antennas in each paddle are uniquely positioned with the appropriate overlap to cancel out mutual coupling effects from adjacent antennas. Pre-amplifier decoupling reduces any remaining decoupling between the antennas. The paddles are held in place over the imaging area via a headband. A system interface cable connects to the coil at the top of the headband. The foam paddles connect to the headband using a ball and socket joint that enable proper positioning of the paddles over the imaging area. To ensure safety, each antenna is equipped with two transmit decoupling circuits; one active and the other passive. Active decoupling is achieved by PIN 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 switched detune the antennas further during RF transmit.
Predicate Devices:	Machnet Carotids Coil Array Assembly (K012491) USAI 3T HD Breast Array (K052585) USAI Millennium III 3T-8-Channel Neurovascular Coil (K042342)
Comparison to Predicate:	It is our opinion that the NeoCoil 3.0T 6-Channel Carotid Array Coil in this submission is substantially equivalent to the previously cleared Machnet Carotids Coil Array Assembly (K012491), the USAI 3T HD Breast Array (K052585), and the USAI Millennium III 3T-8-Channel Neurovascular Coil (K042342). Remaining differences do not impact indications for use or have an impact on safety.
Summary of Studies:	In all material respects, the NeoCoil 3.0T 6-Channel Carotid Array is substantially equivalent to the Machnet Carotids coil Assembly. SNR and image uniformity testing was performed which support the conclusion that the submitted device satisfies design objectives.
Conclusion:	The NeoCoil 3.0T 6-Channel Carotid Array is substantially equivalent to the predicate device. Use of the NeoCoil 3.0T 6-Channel Carotid Array does not result in any new potential hazards and does not alter the safety of the MRI scanner.

Appendix F: Preliminary Product Data Sheet

Neocoil

3.0T 6-Channel Carotid Array Coil

The 3.0T 6-Channel Carotid Array Coil enables bilateral diagnostic imaging of the carotid artery bifurcation using a GE Signa® 3.0T EXCITE® HD series MR system.

Primary Applications

The 3.0T 6-Channel Carotid Array Coil has been designed and tested to provide high quality imaging of the carotid arteries. The unique array configuration offers complete coverage head and neck vasculature from the sternal notch through the internal carotid arteries at the level of cervical vertebrae C1. The coil allows for sub-millimeter resolution of the carotids lumen, vessel walls, and atherosclerotic plaques.

Technical Features

This phased-array coil has 6 elements. The element configuration is optimized to provide deep penetration SNR and improved S/I coverage.

The unique headband and positioning system facilitate patient setup and fit, providing greater patient comfort and imaging performance.

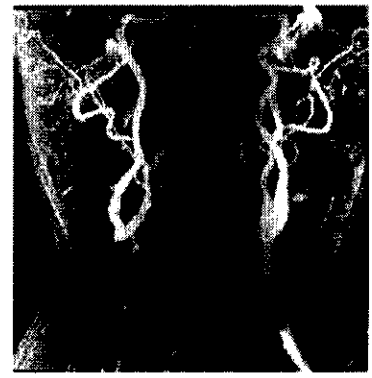
The coil is compatible with ASSET® parallel imaging techniques.

Coil Coverage (FOV)

Superior / Inferior	15cm
Anterior / Posterior	15 cm
Right / Left	24 cm

Coil Dimensions

Length	17.5 cm	6.9 in
Width	28.0 cm	11.0 in
Height	48.0 cm	18.9 in
Weight	1.5 kg	3.4 lbs



System Requirements and Ordering

Requires a GE 3.0T Signa EXCITE HD series MR system. Compatible with all such models. Offered by GE through catalog MTBD, or NeoCoil catalog number NC001.

Warranty

The published Company warranty in effect on the date of shipment shall apply. The Company reserves the right to make changes.

Manufactured by NeoCoil, LLC.

NeoCoil, LLC
N27 W23810A Paul Rd.
Pewaukee, WI 53072

Third Party Review Quality Assessment

Section 1 – Submission Information

510(k) No.: K070778 Third Party Organization: Intertek Testing Services NA, Inc.

Third Party's Primary Reviewer(s): Daniel Lehtonen

ODE/OIVD Division: DRARD Branch/Team: Radiological Devices Branch

Section 2 – 510(k) Decision

Third party recommendation: SE √ NSE ____ Other (specify): _____

ODE/OIVD final decision: SE √ NSE ____ Other (specify): _____

Section 3 – Assessment of Third Party Review

Review Element	Rating (check one)		
	Adequate	Minor Issue(s)	Major Issue(s)
a. Determination of device eligibility for third party review	√		
b. Extent of pre-submission consultation with ODE/OIVD division			
c. Organization and format of review documentation	√		
d. Determination of 510(k) administrative completeness (screening review)	√		
e. Summary of device characteristics, intended use, and performance (including accessories, if applicable) and reason for 510(k) submission	√		
f. Comparison to legally marketed devices—identification and analysis of key similarities and differences		√	
g. Rationale for conclusions and recommendation	√		
h. Use of guidance documents and standards	√		
i. Resolution of 510(k) deficiencies and FDA requests for additional information			
j. Scope of reviewer expertise and use of consulting reviewers			
k. Other (specify):			

Comments (explanation of ratings/issues): The performance of the coil did not match the labeling, IFU and 510(k) summary. This was corrected by the Sponsor after I requested additional information.

Section 4 – ODE/OIVD Assessor Information

Assessed by: Sunder Rajan Date: April 5, 2007 Tel. No.: 240 276 3968

Routing: Division--Clip completed assessment (this page only) to inside front cover of 510(k).
DMC--Forward this page only to Eric Rechen, POS/ODE, Rm. 120J, Corp. Blvd. (HFZ-402).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

NeoCoil
c/o Mr. Daniel W. Lehtonen
Staff Engineer – Medical Devices and
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

APR 11 2007

Re: K070778
Trade/Device Name: NeoCoil 3.OT 6-Channel Carotid Array Coil
Regulation Number: 21 CFR §892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: March 20, 2007
Received: March 21, 2007

Dear Mr. Brown:

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.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" (21 CFR 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 (301) 443-6597 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): K070778

Device Name: NeoCoil 3.0T 6-Channel Carotid Array Coil

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David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070778

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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