K141832
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NeoCoil

JUL 3 1 2014

5. Traditional 510(k) Summary

5.1. Applicant
NeoCoil, LLC
N27 W23910A Paul Rd
Pewaukee, WI 53072 USA

5.2. Contact
Michael Leigh
Director, Regulatory/Quality
262-522-6127 (direct)
261-347-1251 (fax)
Mike.leigh@neocoil.com

5.3. Preparation Date
07/03/2014

5.4. Name of Device
- Proprietary Name: 3T 16ch Flex SPEEDER Coils
- Common Name: Magnetic Resonance Specialty Coil
- Classification: 21 CFR 892.1000, Product Code MOS

5.5. Model Numbers

NeoCoil Model Number	NeoCoil Model Name	Toshiba Model Number
NC045000	3T 16ch Flex SPEEDER Coil, Medium	MJAJ-212A
NC046000	3T 16ch Flex SPEEDER Coil, Large	MJAJ-222A

5.6. Device Description
The NeoCoil 3T 16ch Flex SPEEDER Coils are a receive-only phased array coil system designed to provide high resolution imaging for the upper and lower extremities, chest, abdomen, pelvis, head, neck, and spine. The system is compatible with 2D, 3D, parallel and isotropic imaging, as well as, coil signal intensity correction. The system consists of:
- Two formable, flexible and detachable antennae of different size that can be wrapped or orientated flat, in order to accommodate various anatomic shapes and sizes.
- Optional accessories designed for patient comfort and reduced motion artifacts.

The NeoCoil 3T 16ch Flex SPEEDER Coils are tuned to receive RF frequency corresponding to the proton precession in a 3 tesla magnetic field, which is governed by the Larmor equation.

5.7. Predicate Device
- 1.5T 16ch Flex SPEEDER Coil, K121362 as cleared on 06/15/2012.

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5.8. Comparison to Predicate

The NeoCoil 3T 16ch Flex SPEEDER Coils are similar in physical, performance, design and material characteristics to the legally marketed device, the 1.5T 16ch Flex SPEEDER, K121362, as cleared on 06/15/2012.

The differences introduced in this submission include:

- DC and RF chains have been modified to meet the Toshiba Vantage Titan 3T Coil Interface Description.
- Additional decoupling circuit in the 3T 16ch Flex SPEEDER Large compared to the 1.5T 16ch Flex SPEEDER Large for the purpose of improved uniformity.
- Compared to the 1.5T 16ch Flex SPEEDER, the preamplifier circuitry was moved from the antenna housing, to the cable, within a pre-amp cover located further away from the imaging volume to improve stability.

The Indications for Use are consistent with the capabilities of the predicate device, the NeoCoil 1.5T 16ch Flex SPEEDER Coil, K121362 as cleared on 06/15/2012.

Clinical testing demonstrates that the differences in the devices do not affect the safety and/or the effectiveness of the device when used as labeled.

5.9. Indications for Use

To be used in conjunction with Toshiba 3T Magnetic Resonance Scanners with ODU connectors to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck and spine that can be interpreted by a trained physician.

5.10. Intended Use

Intended use of the 3T 16ch Flex SPEEDER Coils is identical to that of routine MR imaging; specifically to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck, and spine.

Use of the device in conjunction with an MRI scanner is unchanged.

5.11. Testing

The following data has been submitted, referenced or relied on to demonstrate that the NeoCoil 3T 16ch Flex SPEEDER Coils are safe and effective. The devices' performance meets the requirements of pre-defined acceptance criteria and intended uses.

Performance testing - Bench:

Test	Pass/Fail Criteria	Result
Unplugged Surface Temperature	Acceptable level of risk	**Pass:** Surface temperature is not greater than 41°C when the coil is left unplugged in the MRI scanner.
Surface Temperature	Pre-defined performance standards	**Pass:** RF and Eddy current heating is not greater than 41°C.
Blocking Network Analysis	Adequate transmit decoupling	**Pass:** Blocking network demonstrates adequate active and passive transmit decoupling.

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Test	Pass/Fail Criteria	Result
B1 Field Distortion	Pre-defined performance standards	**Pass:** B1 field inhomogeneity meets Toshiba performance requirements and demonstrates adequate active and passive transmit decoupling.
NEMA MS 6-2008	Pre-defined performance standards	**Pass:** SNR and Image Uniformity are consistent with the requirements for indications for use.

Published Standards testing:

Standard	Purpose
IEC 60601-1	Electromechanical safety
IEC 60601-1-2	ESD
IEC 60601-2-33	Electromechanical safety
ISO 10993-1	Biocompatibility
NEMA MS-6	SNR and Image Uniformity

Performance testing - Clinical:

The clinical data in this section exhibits a mix of technical factors and anatomy in the axial, sagittal and coronal planes as recommended in the FDA guidance, *Guidance for the Submission Of Premarket Notifications for Magnetic Resonance Diagnostic Devices*, issued November 14, 1998.5

No adverse events were reported during clinical performance testing; the 3T 16ch Flex SPEEDER Coil, Large and 3T 16ch Flex SPEEDER Coil, Medium demonstrated performance adequate to support the Indications for Use.

5.12. Conclusion

This submission demonstrates that the Indications for Use are in line with the predicate device to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck, and spine and are as safe and effective as the predicate device. As such, the 3T 16ch Flex SPEEDER Coils are equivalent to their predicate, 1.5T 16ch Flex SPEEDER Coil, K121362 as cleared on 06/15/2012.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

NEOCOIL, LLC
MICHAEL LEIGH
N27 W23910A PAUL RD.
PEWAUKEE WI 53072

July 31, 2014

Re: K141832
Trade/Device Name: 3t 16ch Flex Speeder, Medium , 3t 16ch Flex Speeder, Large
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: July 3, 2014
Received: July 7, 2014

Dear Mr. Leigh:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041

or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k141832

Device Name
3T 16ch Flex SPEEDER Coils

Indications for Use *(Describe)*

To be used in conjunction with Toshiba 3T Magnetic Resonance Scanners with ODU connectors to produce diagnostic images of the upper and lower extremities, chest, abdomen, pelvis, head, neck and spine that can be interpreted by a trained physician.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Michael D. O'Hara

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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