November 16, 2018

NeoCoil, LLC
Katie Gonzalez
Regulatory & Quality Engineering Manager
N27 W23910 A Paul Rd.
Pewaukee, Wisconsin 53072

Re: K182958
Trade/Device Name: 1.5T 16ch Breast Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: October 22, 2018
Received: October 24, 2018

Dear Katie Gonzalez:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Robert A. Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182958

Device Name

1.5T 16ch Breast Coil

Indications for Use *(Describe)*

To be used in conjunction with GEHC 1.5T Magnetic Resonance Scanners to produce diagnostic and interventional planning images of the breast that can be interpreted by a trained physician. When used with biopsy accessories, this device permits access to the breast anatomy for interventional procedures that can be performed 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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5. Traditional 510(k) Summary

5.1. Applicant

NeoCoil, LLC
N27 W23910A Paul Rd
Pewaukee, WI 53072 USA

5.2. Contact

Katie Gonzalez
Regulatory & Quality Engineering Manager
262-522-6124 (direct)
261-347-1251 (fax)
Katie.Gonzalez@neocoil.com

5.3. Preparation Date

October 22, 2018

5.4. Name of Device

- Proprietary Name: 1.5T 16ch Breast Coil
- Common Name: Magnetic Resonance Specialty Coil
- Classification: 21 CFR 892.1000, Product Code MOS

5.5. Model Numbers

NeoCoil Model Number	NeoCoil Model Name
NC091203	Baseplate Assy, Breast Coil, 1.5T
NC091200	Medial Array, Breast Coil, 1.5T
NC091201	Lateral Array, Breast Coil, 1.5T Left
NC091202	Lateral Array, Breast Coil, 1.5T Right
NC091207	Biopsy Array, 1.5T Left
NC091208	Biopsy Array, 1.5T Right

5.6. Device Description

The NeoCoil 1.5T 16ch Breast Coil is a phased array coil for imaging structures of the breast, axilla and chest wall. The 1.5T 16ch Breast Coil is a three part receive-only coil designed to provide high resolution imaging. The 1.5T 16ch Breast Coil includes a coil support structure, patient support structure, biopsy components and comfort pads.

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The NeoCoil 1.5T 16ch Breast Coil is tuned to receive RF frequency corresponding to the proton precession in a 1.5 tesla magnetic field, which is governed by the Larmor equation.

The NeoCoil 1.5T 16ch Breast Coil is intended for use in a manner that is identical to the predicate device described in this submission.

5.7. Predicate Device

- NeoCoil 3.0T 16ch Breast Coil, K173377, as cleared on 11/28/2017.

5.8. Comparison to Predicate

The NeoCoil 1.5T 16ch Breast Coil is similar in physical, performance, design and material characteristics to the legally marketed device, the NeoCoil 3.0T 16ch Breast Coil, K173377, as cleared on 11/28/2017.

With the exception of the field strength, the Indications for Use are identical with the predicate device, the NeoCoil 3.0T 16ch Breast Coil, K173377, as cleared on 11/28/2017.

Clinical testing demonstrates that the differences in the field strength of 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 GEHC 1.5T Magnetic Resonance Scanners to produce diagnostic and interventional planning images of the breast that can be interpreted by a trained physician. When used with biopsy accessories, this device permits access to the breast anatomy for interventional procedures that can be performed by a trained physician.

5.10. Intended Use

Intended use is identical to that of routine imaging; specifically to produce diagnostic and interventional planning images of the breasts, axilla and chest wall.

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 1.5T 16ch Breast Coil is safe and effective. The device's 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.
B1 Field Distortion	Pre-defined performance standards	**Pass:** B1 field inhomogeneity meets performance requirements and demonstrates adequate active and passive transmit decoupling**.**

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Test	Pass/Fail Criteria	Result
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 60601-1-6	Usability
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 as recommended in the FDA guidance, *Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices issued November 18, 2016.*

No adverse events were reported during clinical performance testing; the 1.5T 16ch Breast Coil 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 breasts, axilla and chest wall and are as safe and effective as the predicate device. As such, the 1.5T 16ch Breast Coil is equivalent to the predicate, NeoCoil 3.0T 16ch Breast Coil, K173377, as cleared on 11/28/2017.