October 14, 2022

NeoCoil, LLC
% Katie Gonzalez
Quality Systems & Regulatory Manager
N27 W23910A Paul Road
PEWAUKEE WI 53072

Re: K222407
Trade/Device Name: 16ch Breast Coil / 16ch Breast Coils, 1.5T 16ch Breast Coil, 3.0T 16ch Breast Coil, 1.5T 16ch Breast Coil, 3T 16ch Breast Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: MOS
Dated: September 9, 2022
Received: September 15, 2022

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222407

Device Name

16ch Breast Coils: 1.5T 16ch Breast Coil / 3.0T 16ch Breast Coil, 1.5T 16ch Breast Coil / 3T 16ch Breast Coil

Indications for Use *(Describe)*

The NeoCoil 16ch Breast Coils are Magnetic Resonance Imaging (MRI) RF Receive-Only Coils intended for use by trained medical professionals, in combination with and controlled by compatible 1.5T or 3T/3.0T MRI system software.

The NeoCoil 16ch Breast Coils can be used with compatible ancillary components, accessories, and/or devices to provide access to breast anatomy for diagnostic or interventional planning/procedures.

When used as intended, the 16ch Breast Coil provides information used by the MRI system to produce diagnostic and/or interventional planning images of the breast, axilla, and chest wall. The images produced are interpreted by medical professionals as part of clinical decision making.

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.

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Special 510(k) Summary

K222407

Applicant

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

Contact

Katie Gonzalez
Quality Systems and Regulatory Manager
262-522-6124 (office)
262-347-1251 (fax)
Katie.Gonzalez@neocoil.com

Preparation Date

August 3, 2022

Name of Device

- Trade/Proprietary name(s):

  16ch Breast Coils

Submission	Device Trade/Proprietary Name
Existing model	3.0T 16ch Breast Coil
Existing model	1.5T 16ch Breast Coil
New model	3T 16ch Breast Coil
New model	1.5T 16ch Breast Coil

- Common name: Magnetic Resonance Specialty Coil
- Classification name: 21 CFR 892.1000, Magnetic resonance diagnostic device, Product Code MOS

Predicate Device

3.0T 16ch Breast Coil, K173377, cleared on 11/28/2017, manufactured by NeoCoil, LLC

Reference Device

1.5T 16ch Breast Coil, K182958, cleared on 11/16/2018, manufactured by NeoCoil, LLC

Device Description

The NeoCoil 3.0T 16ch Breast Coil is a phased array coil for imaging structures of the breast, axilla and chest wall. The 3.0T 16ch Breast Coil is a three part receive-only coil designed to provide high resolution imaging. The.3.0T 16ch Breast Coil includes a coil support structure, patient support structure, biopsy components, accessories and comfort pads.

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The NeoCoil 3.0T 16ch Breast Coil is tuned to receive RF frequency corresponding to the proton precession in a 3 tesla magnetic field, which is governed by the Larmor equation.

The 16ch Breast Coils are intended for use in a manner that is identical to the predicate device and reference device described in this submission 3.0T 16ch Breast Coil, K173377, cleared on 11/28/2017 and 1.5T 16ch Breast Coil, K182958, cleared on 11/16/2018. The 16ch Breast Coil consists of the following arrays available in 1.5T, 3.0T and 3T field strengths:

- Medial Array, Breast Coil
- Lateral Array Left, Breast Coil
- Lateral Array Right, Breast Coil
- Baseplate Assembly, Breast Coil
- Biopsy Array Left, Breast Coil
- Biopsy Array Right, Breast Coil

The coils receive magnetic resonance signals generated in hydrogen nuclei (protons) in the Head, Neck and Brachial Plexus anatomy while blocking the high-frequency magnetic field applied by the MRI scanner at specified timings. The received signals are amplified before being transferred to the MRI scanner through the coil's system cable. The amplified signals are processed into tomographic images of the breast, axilla and chest wall anatomy by the MRI scanner. Images are typically generated as axial, sagittal, coronal oblique slices. Accessories associated with the 16ch Breast Coils include biopsy grids and biopsy drapes.

The 1.5T Breast Coil, the 3T 16ch Breast Coil, and the 3.0T 16ch Breast Coil are tuned to receive RF frequency corresponding to the proton precession in a 1.5 tesla and 3.0 tesla magnetic field (respectively), which is governed by the Larmor equation.

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

Proposed labeling is documented in the Instructions for Use manual for the 16ch Breast Coil (NC149IFU-en).

Intended Use, including indications

The NeoCoil 16ch Breast Coils are Magnetic Resonance Imaging (MRI) RF Receive-Only Coils intended for use by trained medical professionals, in combination with and controlled by compatible 1.5T or 3T/3.0T MRI system software.

The NeoCoil 16ch Breast Coils can be used with compatible ancillary components, accessories, and/or devices to provide access to breast anatomy for diagnostic or interventional planning/procedures.

When used as intended, the 16ch Breast Coil provides information used by the MRI system to produce diagnostic and/or interventional planning images of the breast, axilla, and chest wall. The images produced are interpreted by medical professionals as part of clinical decision making.

Technological Characteristics

16ch Breast coils are similar in design, material, chemical composition and energy source to the legally marketed predicate device and reference device described in this submission 3.0T 16ch Breast Coil, K173377, cleared on 11/28/2017 and 1.5T 16ch Breast Coil, K182958, cleared on 11/16/2018.

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At a high level, the 16ch Breast Coils included as part of this submission, and the predicate device, 3.0T 16ch Breast Coil (K173377) are based on the following same technological elements:

- Prescription use;
- Coil designs are receive-only phased array coils;
- Preamplification methodology
- Decoupling methodology
- Patient contacting materials and chemical composition are known materials that have been assessed for compliance with recognized biocompatibility standards;
- Energy source for the coils is the MRI scanner;
- Energy is not intended to be supplied by the coils;
- Mechanical designs are contoured for the breast anatomy;
- Facilitates imaging for diagnostic and interventional planning of the breast, axilla and chest wall anatomy;
- Channel count
- Field strength when compared to the predicate device and reference device

The following technological differences exist between the subject and predicate and reference devices:

- MRI specific system cabling
- MRI specific interface circuitry
- MRI specific RF loop and preamplifier tuning
- Addition of fuses on antenna elements

Testing performed per defined standards demonstrates that the safety and/or effectiveness of the 16ch Breast Coils compared to the predicate device is not adversely affected as a result of the differences.

Testing

Through NeoCoil's design controls process, a risk assessment leveraging FDA's guidance document decision trees for when to submit a new 510(k) for changes to an existing device, a summary of non-clinical performance data using well-established methodologies is included, referenced, or relied on to demonstrate that the 16ch Breast Coils are safe and effective and performs in a manner that demonstrates substantial equivalence to the predicate device and reference device described in this submission 3.0T 16ch Breast Coil, K173377, cleared on 11/28/2017 and 1.5T 16ch Breast Coil, K182958, cleared on 11/16/2018.

Performance testing - Bench:
A Test Report Summary for non-clinical Bench Testing performed, including testing to FDA-recognized consensus standards identified as relevant in FDA guidance document Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices, issued November 18, 2016, is outlined below:

Test Performed	Objective(s) of the Test	Test Method Description	Pre-defined pass/fail criteria	Results Summary	Discussions / Conclusions
Biocompatibility Assessment	Assess potential biological risks	Evaluation of data; historical use, biologic testing, where warranted	Acceptable level of risk	Pass	No identified significant risks.

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Test Performed	Objective(s) of the Test	Test Method Description	Pre-defined pass/fail criteria	Results Summary	Discussions / Conclusions
Electrical Safety	Basic electrical safety/essential performance, 60601-1	Test Lab	Pre-defined performance standards	Pass	Applicable requirements for basic electrical safety and essential performance met.
Electrical Safety	Particular electrical requirements; MR equipment, 60601-2-33	Test Lab	Pre-defined performance standards	Pass	Applicable requirements of the particular standard were met.
Electrical Safety	Collateral electrical safety/essential performance, 60601-1-2	Test Lab / Bench Testing	Pre-defined performance standards	Pass	Applicable requirements of the collateral standard were met.
Usability Assessment	Devices meet customer, end user and patient needs	Actual, simulated or retrospective evaluation of the device and/or data	Pre-defined requirements	Pass	The devices met the needs of the customer, end user and patient.
Entrapment, Trapping Zone and Cable Looping (assessment w/ scanner)	Assess the device for pinch points, entrapment, cable looping – interfacing with MRI scanner	Evaluation of coil-to-scanner entrapment, trapping and cable looping not covered by test lab assessments.	Requirements based on pre-defined requirements in 60601-1 and customer requirements	Pass	Requirements were met.
Surface Temperature	Surface temperatures do not exceed limits	MRI scanner test	Pre-defined performance standards	Pass	Surface temperatures were within IEC limits.
Unplugged Surface Temperature	Devices remain safe in first fault condition	MRI scanner test	Acceptable level of risk	Pass	Surface temperatures were within IEC limits when the coil is left unplugged in the MRI scanner.
Blocking Network Analysis	Ensures devices are designed with adequate active and passive transmit decoupling	Theoretical calculations	Adequate transmit decoupling	Pass	Blocking network demonstrates adequate active and passive transmit decoupling.
B1 Field Distortion	Measure amount of distortion produced due to presence of an RF coil in the scanner	MRI scanner test	Pre-defined performance standards	Pass	B1 field inhomogeneity meets performance requirements and demonstrates adequate active and passive transmit decoupling.

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Test Performed	Objective(s) of the Test	Test Method Description	Pre-defined pass/fail criteria	Results Summary	Discussions / Conclusions
B0 Filed Distortion	Measure amount of distortion produced due to presence of an RF coil in the scanner	MRI scanner test	Pre-defined performance standards	Pass	B0 field inhomogeneity meets performance requirements and demonstrates adequate active and passive transmit decoupling.
NEMA MS 6-2008	Evaluate single-channel non-volume special purpose radiofrequency (RF) coils for use with magnetic resonance (MR) imaging (MRI) systems	MRI scanner test	Pre-defined performance standards	Pass	SNR and Image Uniformity are consistent with the requirements for indications for use.

Performance testing - Clinical:
Due to the substantial equivalency of the devices and the evaluation of performance testing against defined standards, no additional clinical performance testing has been performed above that present for the predicate device and reference device described in this submission 3.0T 16ch Breast Coil, K173377, cleared on 11/28/2017 and 1.5T 16ch Breast Coil, K182958, cleared on 11/16/2018.

No adverse events have been reported against the predicate device and reference device described in this submission 3.0T 16ch Breast Coil, K173377, cleared on 11/28/2017 and 1.5T 16ch Breast Coil, K182958, cleared on 11/16/2018.

Conclusion

This submission demonstrates by means of nonclinical testing that the 16ch Breast Coils are substantially equivalent to and perform as well as the predicate device and reference device described in this submission 3.0T 16ch Breast Coil, K173377, cleared on 11/28/2017 and 1.5T 16ch Breast Coil, K182958, cleared on 11/16/2018.