April 23, 2026

NeoCoil, LLC
Judy Yuan
Sr. Regulatory Affairs Specialist
N27 W23910A Paul Rd.
Pewaukee, Wisconsin 53072

Re: K260947
Trade/Device Name: 0.55T 12Ch Breast Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: April 6, 2026
Received: April 6, 2026

Dear Judy Yuan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260947

Please provide the device trade name(s).

0.55T 12Ch Breast Coil

Please provide your Indications for Use below.

The NeoCoil 12Ch Breast Coil is a Magnetic Resonance Imaging (MRI) RF Receive-Only Coil intended for use by trained medical professionals, in combination with and controlled by compatible 0.55T MRI system software.

The NeoCoil 12Ch Breast Coil 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 12Ch 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

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Special 510(k) Summary

K260947

Applicant

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

Contact

Judy Yuan
Sr. Regulatory Affairs Specialist
262-522-6124 (office)
262-347-1251 (fax)
Judy.Yuan@neocoil.com

Preparation Date

March 27, 2026

Name of Device

- Trade/Proprietary name(s): 0.55T 12Ch Breast Coil
- Common name: Magnetic Resonance Specialty Coil
- Classification name: 21 CFR 892.1000, Magnetic resonance diagnostic device, Product Code MOS

Predicate Device

1.5T and 3T 16ch Breast Coil, K222407, cleared on 10/14/2022, manufactured by NeoCoil, LLC

Device Description

The NeoCoil 0.55T 12Ch Breast Coil is similar in physical and material characteristics and similar in design characteristics to NeoCoil's legally marketed devices, the 3T and 1.5T 16Ch Breast Coil, K222407, as cleared on 10/14/2022.

The NeoCoil 12Ch Breast Coil is a phased array coil for imaging structures of the breast, axilla, and chest wall. It is a three parts receive-only coil designed to provide high resolution imaging. The 12Ch Breast Coil consists of a coil support structure, patient support structure, biopsy accessories, and comfort pads.

The left and right Lateral Arrays are comprised of three channels each. The left and right Biopsy Arrays are comprised of one channel each. The Medial Array is comprised of six channels, three on the left and three on the right. All of the arrays are connectorized to allow detaching from the coil support structure. Within the fixed rails on the Baseplate are a left and right carriage on to which the side specific Lateral and Biopsy Arrays will lock into place to allow for lateral movement. Left and Right Biopsy Risers can be used to make access to posterior anatomy easier, as well as to prevent obstruction of target tissue for patients with larger anatomy. Both rails have position indicators to help you position the arrays at the same field of view. The Medial Array plugs directly into the interface, which is connected to the system cable. The system cable is connected to the Siemens MRI scanner.

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The patient support structure provides head, chest, and abdominal support. The Headrest does not attach to the main coil base so that it can be moved superior or inferior. The height of the Headrest is adjustable and in its base is embedded a mirror to support patient comfort. The Chest Support and Chest Support Pad provide cushioning and support for the shoulders and upper torso. The Abdominal Ramp Pad provides support for the patient's abdomen and hips, and when used with the optional Hip Riser Pad and Wedge Pads provides positioning options to maximize patient comfort. The Arm Pad and optional Arm Riser Pad not only provide patient comfort but also help to keep the patient's hands from forming anatomical loops and from touching the system cable.

Single use, non-sterile grids can easily be installed into the Biopsy Arrays for biopsy procedures. The Lateral Compression Plate covers a single Lateral Array during a medial biopsy, and the Medial Compression Plate covers the Medial Array during a lateral biopsy. In addition, there is a Breast Blocker that keeps the unaffected breast out of the way during medial biopsy procedures.

The 0.55T 12Ch Breast Coil is intended for use in a manner that is identical to the predicate device (1.5T and 3T 16ch Breast Coil, K222407, cleared on 10/14/2022) described in this submission.

The coils receive magnetic resonance signals generated in hydrogen nuclei (protons) in the breast, axilla, and chest wall 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 Breast Coils include biopsy grids and biopsy drapes.

The 0.55T 12Ch Breast Coil, 1.5T 16ch Breast Coil, and 3T 16ch Breast Coil are tuned to receive RF frequency corresponding to the proton precession in a 0.55 tesla, 1.5 tesla and 3 tesla magnetic field (respectively), which is governed by the Larmor equation.

The 12Ch Breast Coil is intended for use in a manner that is identical to the predicate device described in this submission, to provide 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

Proposed labeling is documented in the Instructions for Use manual for the 12Ch Breast Coil (NC150IFU-en).

Intended Use, including indications

The NeoCoil 12Ch Breast Coil is a Magnetic Resonance Imaging (MRI) RF Receive-Only Coil intended for use by trained medical professionals, in combination with and controlled by compatible 0.55T MRI system software.

The NeoCoil 12Ch Breast Coil 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 12Ch 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

0.55T 12Ch Breast coil is similar in design, material, chemical composition and energy source to the legally marketed predicates device (1.5T and 3T 16ch Breast Coil, K222407, cleared on 10/14/2022 described in this submission.

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At a high level, the 12Ch Breast Coil included as part of this submission, and the predicate device (1.5T and 3T 16ch Breast Coil, K222407, cleared on 10/14/2022) described in this submission are based on the following same technological elements:

- Prescription use;
- Coil designs are receive-only phased array coils;
- Fuses on antenna elements
- Preamplification methodology;
- Decoupling methodology;
- Patient contact type and duration of contact; Coil enclosure and cable enclosure material are known materials that have been assessed for compliance with recognized biocompatibility standard;
- Energy source for the coil is the MRI scanner;
- Energy is not intended to be supplied by the coil;
- Mechanical designs are contoured for the breast anatomy;
- Facilitates imaging for diagnostic and interventional planning of the breast, axilla and chest wall anatomy;

The technological differences exist between the subject and predicate devices:

- Usability
  - Biopsy Risers (optional components)
  - LED illumination in biopsy array
  - Patient comfort pads and chest supports
  - Color code labels and connectors
- Electric/EMC
  - MRI specific system cabling
  - MRI specific interface circuitry
  - MRI specific RF loop and preamplifier tuning
  - Channel counts
  - Field strength
- Labeling
  - USB for eIFU

Testing performed per defined standards demonstrates that the safety and/or effectiveness of the 0.55T 12Ch Breast Coil 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 0.55T 12Ch Breast Coil is safe and effective and performs in a manner that demonstrates substantial equivalence to the predicate device (1.5T and 3T 16ch Breast Coil, K222407, cleared on 10/14/2022).

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 on October 10, 2023, is outlined below:

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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.
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.

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Test Performed	Objective(s) of the Test	Test Method Description	Pre-defined pass/fail criteria	Results Summary	Discussions / Conclusions
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.
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 (1.5T and 3T 16ch Breast Coil, K222407, cleared on 10/14/2022).

No adverse events have been reported against the predicate device (1.5T and 3T 16ch Breast Coil, K222407, cleared on 10/14/2022).

Conclusion

The performance tests demonstrate that the device is as safe, as effective, and is substantially equivalent to the predicate device (1.5T and 3T 16ch Breast Coil, K222407, cleared on 10/14/2022).