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

March 11, 2022

Re: K213687
Trade/Device Name: 32Ch AIR Open Coil Suite: 1.5T AIR Open Head Neck Posterior 9ch / 3.0T AIR Open Head Neck Posterior 9ch, 1.5T AIR Open Neck Chest Anterior 7ch / 3.0T AIR Open Neck Chest Anterior 7ch, 1.5T AIR Open Head Anterior 16ch / 3.0T AIR Open Head Anterior 16ch
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: February 23, 2022
Received: February 24, 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 and Part 809); 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K213687

Device Name
32Ch AIR Open Coil Suite: 1.5T AIR Open Head Neck Posterior 9ch / 3.0T AIR Open Head Neck Posterior 9ch, 1.5T AIR Open Neck Chest Anterior 7ch / 3.0T AIR Open Neck Chest Anterior 7ch, 1.5T AIR Open Head Anterior 16ch / 3.0T AIR Open Head Anterior 16ch

Indications for Use *(Describe)*
The 32Ch AIR Open Coil Suite are Magnetic Resonance Imaging (MRI) RF Receive-Only Coils intended to be used by trained medical professionals, for adult patients, in combination with and controlled by 1.5T or 3.0T GE Healthcare MRI system software.

The 32Ch AIR Open Coil Suite is intended for use with specified couchtop and patient immobilization devices depending on the region of interest.

When used as intended, the 32Ch AIR Open Coil Suite is used to produce diagnostic images of the head, neck, and brachial plexus structures. The images can be interpreted by medical professionals or facilitate Radiation Therapy (RT) planning.

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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K213687

Traditional 510(k) Summary

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

November 18, 2021

Name of Device

- Trade/Proprietary name(s):

  32Ch AIR Open Coil Suite

  1.5T 32Ch AIR Open Coil Suite

  1.5T AIR Open Head Neck Posterior 9ch
  1.5T AIR Open Neck Chest Anterior 7ch
  1.5T AIR Open Head Anterior 16ch

  3.0T 32Ch AIR Open Coil Suite

  3.0T AIR Open Head Neck Posterior 9ch
  3.0T AIR Open Neck Chest Anterior 7ch
  3.0T AIR Open Head Anterior 16ch

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

Predicate Device

3.0T GEM RT Open Array, K143389 cleared on 03/06/2015

Device Description

The 32Ch AIR Open Coil Suite is comprised of MRI receive-only phased array RF coils designed for clinically acceptable signal-to-noise ratio (SNR) and uniform coverage of the Head, Neck and Brachial Plexus anatomy for use with GE Healthcare Magnetic Resonance Imaging (MRI)

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scanners. The 32Ch AIR Open Coil Suite consists of the following arrays available in 1.5T and 3.0T field strengths:

- AIR Open Head Neck Posterior 9ch
- AIR Open Neck Chest Anterior 7ch
- AIR Open Head Anterior 16ch

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 by the MRI scanner into tomographic images of the Head, Neck and Brachial Plexus anatomy by the MRI scanner. Images are typically generated as axial, sagittal, coronal oblique slices. There are no accessories associated with the 32Ch AIR Open Coil Suite. Depending on the region of interest, the coils may be used in combination with the CIVCO RT Universal Couchtop™ MR Overlay for GE Motus, Kizuna, and GEM as well as the associated patient immobilization devices (e.g., thermoplastic mask, straps provided with the MRI scanner)

The 1.5T 32Ch AIR Open Coil Suite and the 3.0T 32Ch AIR Open Coil Suite 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 32Ch AIR Open Coil Suite 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 32Ch AIR Open Coil Suite (NC139IFU-en).

Intended Use, including indications

The 32Ch AIR Open Coil Suite are Magnetic Resonance Imaging (MRI) RF Receive-Only Coils intended to be used by trained medical professionals, for adult patients, in combination with and controlled by 1.5T or 3.0T GE Healthcare MRI system software.

The 32Ch AIR Open Coil Suite is intended for use with specified couchtop and patient immobilization devices depending on the region of interest.

When used as intended, the 32Ch AIR Open Coil Suite is used to produce diagnostic images of the head, neck, and brachial plexus structures. The images can be interpreted by medical professionals or facilitate Radiation Therapy (RT) planning.

Technological Characteristics

32Ch AIR Open Coil Suite coils are similar in design, material, chemical composition and energy source to the legally marketed device, the 3.0T GEM RT Open Array, K143389 cleared on 03/06/2015.

At a high level, the 1.5T 32Ch AIR Open Coil Suite and the 3.0T 32Ch AIR Open Coil Suite included as part of this submission, and the predicate device are based on the following same technological elements:

- Prescription use;
- Coil designs are receive-only phased array coils;
- Decoupling methodology;

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- 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;
- No energy is supplied by the coils;
- Coils designs are targeted for the head, neck and brachial plexus anatomy;
- Mechanical designs are contoured for the head, neck and brachial plexus anatomy;
- Facilitate Radiation Therapy (RT) planning;
- Manufactured for use with the same MRI scanner manufacturer.

The following technological differences exist between the subject and predicate device:

- Optimized coil dimensions and geometry to support use on state-of-the-art MRI scanners and improve usability.
- Field strength for the 1.5T 32Ch AIR Open Coil Suite
- Channel count

The Indications for Use for the 1.5T 32Ch AIR Open Coil Suite and 32Ch AIR Open Coil Suite are similar to the predicate device, the 3.0T GEM RT Open Array, K143389 cleared on 03/06/2015.

Clinical and non-clinical testing demonstrates that the safety and/or effectiveness of the 32Ch AIR Open Coil Suites compared to the predicate device is not adversely affected as a result of the differences.

Testing

A combination of clinical and non-clinical performance data is included, referenced, or relied on to demonstrate that the 32Ch AIR Open Coil Suite is safe and effective and performs in a manner that demonstrates substantial equivalence to the predicate device, the 3.0T GEM RT Open Array, K143389 cleared on 03/06/2015.

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.
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.

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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	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.
Maximum B1 Peak	Demonstrate the devices can withstand the maximum B1 peak without obvious signs of arcing, burning, voltage breakdown	MRI scanner test and visual inspection	Pre-defined performance standards	Pass	Coils were able to withstand maximum B1 peak without obvious signs of arcing, burning or voltage breakdown.
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.

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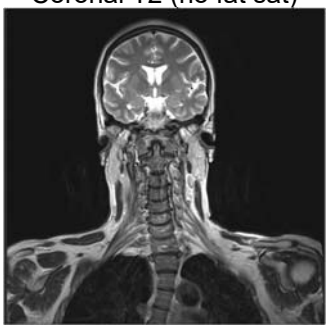
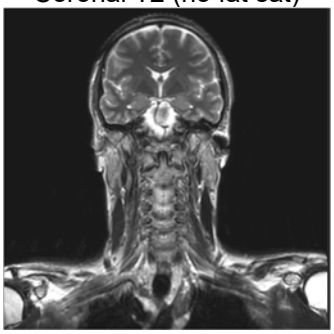
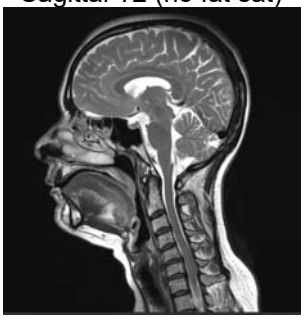
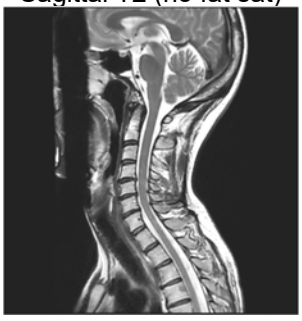
Test Performed	Objective(s) of the Test	Test Method Description	Pre-defined pass/fail criteria	Results Summary	Discussions / Conclusions
NEMA MS 6-2008	Evaluate single-channel non-volume special purpose radiofrequency (RF) coils for use with magnetic resonance (MR) imaging (MRI) systems	MRI scanner test	Pre-defined performance standards	Pass	SNR and Image Uniformity are consistent with the requirements for indications for use.

Performance testing - Clinical:
Clinical data exhibits a mix of technical factors and anatomy as recommended in FDA guidance; Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices issued November 18, 2016.

No adverse events were reported during clinical performance testing.

1.5T 32Ch AIR Open Coil Suite	3.0T 32Ch AIR Open Coil Suite
Coronal T2 (no fat sat) 	Coronal T2 (no fat sat) 
Sagittal T2 (no fat sat) 	Sagittal T2 (no fat sat) 

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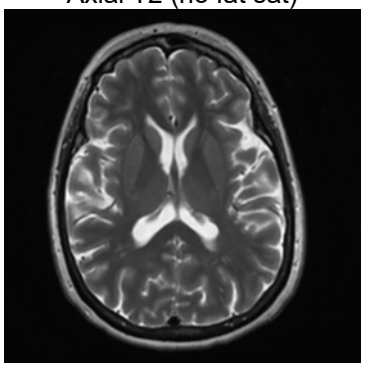
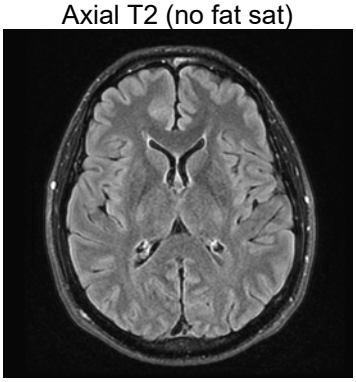
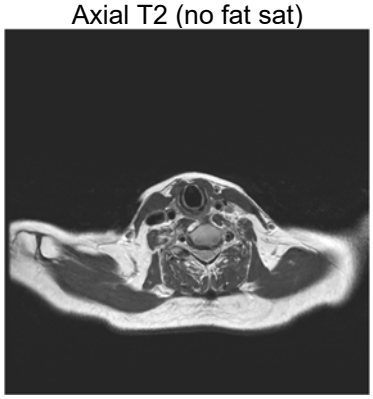
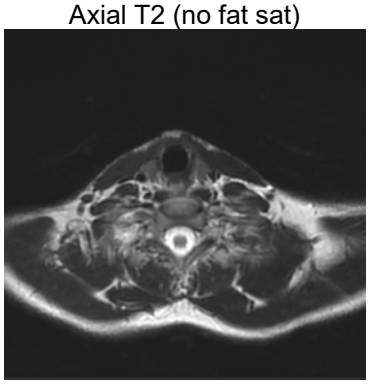
1.5T 32Ch AIR Open Coil Suite	3.0T 32Ch AIR Open Coil Suite
Axial T2 (no fat sat) 	Axial T2 (no fat sat) 
Axial T2 (no fat sat) 	Axial T2 (no fat sat) 

Conclusion

This submission demonstrates by means of nonclinical and clinical testing that the 32Ch AIR Coil Suite are safe and effective and perform as well as or better than the predicate device, the 3.0T GEM RT Open Array, K143389 cleared on 03/06/2015 for the indications claimed.