



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

June 2, 2020

Re: K201101

Trade/Device Name: 1.5T 16ch Shoulder Coil, 3.0T 16ch Shoulder Coil  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance diagnostic device  
Regulatory Class: Class II  
Product Code: MOS  
Dated: April 22, 2020  
Received: April 24, 2020

Dear Ms. 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](mailto: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

## Indications for Use

510(k) Number (if known)

**K201101**

Device Name

1.5T 16ch Shoulder Coil

Indications for Use (Describe)

To be used in conjunction with GEHC 1.5T Magnetic Resonance Scanners to produce diagnostic images of the shoulder 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)

### 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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## Indications for Use

510(k) Number (if known)

K201101

Device Name

3.0T 16ch Shoulder Coil

Indications for Use (Describe)

To be used in conjunction with GEHC 3.0T Magnetic Resonance Scanners to produce diagnostic images of the shoulder 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)

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K201101

## 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 (office)  
262-347-1251 (fax)  
[Katie.Gonzalez@neocoil.com](mailto:Katie.Gonzalez@neocoil.com)

### 5.3. Preparation Date

April 22, 2020

### 5.4. Name of Device

- Trade/Proprietary name(s): 1.5T 16ch Shoulder Coil  
3.0T 16ch Shoulder Coil
- Common name: Magnetic Resonance Specialty Coil
- Classification name: 21 CFR 892.1000, Magnetic resonance diagnostic device, Product Code MOS

### 5.5. Predicate Device

NeoCoil 3.0T 8-Channel Shoulder Array Coil, K071611 cleared on 06/28/2007.

### 5.6. Device Description

The 1.5T 16ch Shoulder Coil and 3.0T 16ch Shoulder Coil are receive-only phased array RF coils designed for optimum signal-to-noise ratio (SNR) and uniform coverage of the shoulder anatomy for use with GE Healthcare Magnetic Resonance Imaging (MRI) scanners. The coils receive magnetic resonance signals generated in hydrogen nuclei (protons) in the shoulder while blocking the high-frequency magnetic field applied by the MRI scanner at specified timings.

Images are typically generated as axial, sagittal, coronal oblique slices and include coverage of the Humerus, Humeral Head, Labrum, Labral Tear, Glenoid, Scapula, Clavicle, and Rotator Cuff regions of the shoulder anatomy.

The 1.5T 16ch Shoulder Coil and 3.0T 16ch Shoulder 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 1.5T 16ch Shoulder Coil and 3.0T 16ch Shoulder Coil are 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 manuals for the 1.5T 16ch Shoulder Coil (NC143IFUF-EN) and 3.0T 16ch Shoulder Coil (NC143IFU-EN).

#### 5.7. Intended Use

The intended use for the 1.5T 16ch Shoulder Coil and the 3.0T 16ch Shoulder Coil are identical to that of the predicate device, the 3.0T 8-Channel Shoulder Array Coil, K071611 cleared on 06/28/2007.

The intended use is:

Identical to that of routine imaging; specifically to produce diagnostic images of the shoulder.

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

#### 5.8. Indications for Use

##### 1.5T 16ch Shoulder Coil:

To be used in conjunction with GEHC 1.5T Magnetic Resonance Scanners to produce diagnostic images of the shoulder that can be interpreted by a trained physician.

##### 3.0T 16ch Shoulder Coil:

To be used in conjunction with GEHC 3.0T Magnetic Resonance Scanners to produce diagnostic images of the shoulder that can be interpreted by a trained physician.

#### 5.9. Technological Characteristics

Both the 1.5T 16ch Shoulder Coil and the 3.0T 16ch Shoulder Coil are similar in design, material, chemical composition and energy source to the legally marketed device, the 3.0T 8-Channel Shoulder Array Coil, K071611 cleared on 06/28/2007.

At a high level, the 1.5T 16ch Shoulder Coil and the 3.0T 16ch Shoulder Coil 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;
- 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 imaging the shoulder anatomy;
- Mechanical designs are contoured for the shoulder anatomy;
- Manufactured for use with the same MRI scanner manufacturer.

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

- The exterior of the predicate device is a flexible foam whereas the 1.5T 16ch Shoulder Coil and 3.0T 16ch Shoulder Coil exterior is comprised of a rigid posterior array and a flexible anterior array;
- Predicate device incorporates 8 channels whereas the 1.5T 16ch Shoulder Coil and the 3.0T 16ch Shoulder Coil incorporate 16 channels;

- Different system cable connectors for the 1.5T 16ch Shoulder Coil and the 3.0T 16ch Shoulder Coil compared to the predicate to interface with the newer MRI scanners.
- Field strength for the 1.5T 16ch Shoulder Coil

The Indications for Use for the 1.5T 16ch Shoulder Coil is similar to the predicate device, the 3.0T 8-Channel Shoulder Array Coil, K071611 cleared on 06/28/2007 differing in compatible scanner(s) and field strength.

With the exception of compatible scanner(s), the Indications for Use for the 3.0T 16ch Shoulder Coil are identical to the 3.0T 8-Channel Shoulder Array Coil, K071611 cleared on 06/28/2007.

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

Clinical and non-clinical testing demonstrates that the safety and effectiveness of the 1.5T 16ch Shoulder Coil compared to the predicate device is not adversely affected as a result of the differences.

#### 5.10. Testing

A combination of clinical and non-clinical performance data is included, referenced or relied on to demonstrate that the 1.5T 16ch Shoulder Coil and 3.0T 16ch Shoulder Coil are safe and effective and perform in a manner that demonstrates substantial equivalence to the predicate device, the 3.0T 8-Channel Shoulder Array Coil, K071611 cleared on 06/28/2007.

#### **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.

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.

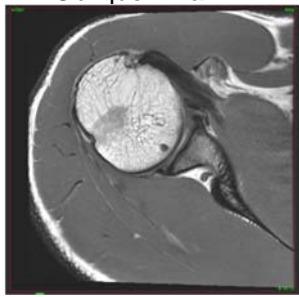


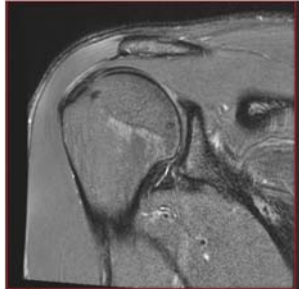


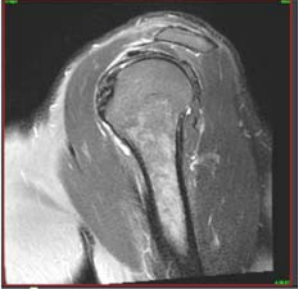

Test Performed	Objective(s) of the Test	Test Method Description	Pre-defined pass/fail criteria	Results Summary	Discussions / Conclusions
NEMA MS 6-2008	Evaluate single-channel non-volume special purpose radio-frequency (RF) coils for use with magnetic resonance (MR) imaging (MRI) systems	MRI scanner 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 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.

1.5T 16ch Shoulder Coil	3.0T 16ch Shoulder Coil
Oblique Axial PD 	Oblique Axial PD 
Oblique Coronal T1 (no fat sat) 	Oblique Coronal T1 (no fat sat) 
Oblique Sagittal T2 (no fat sat) 	Oblique Coronal T2 (fat sat) 

1.5T 16ch Shoulder Coil	3.0T 16ch Shoulder Coil
<p data-bbox="423 289 750 321">Oblique Sagittal T2 (fat sat)</p> 	<p data-bbox="862 289 1224 321">Oblique Sagittal T2 (no fat sat)</p> 

#### 5.11. Conclusion

This submission demonstrates by means of nonclinical and clinical testing that the 1.5T 16ch Shoulder Coil and 3.0T 16ch Shoulder Coil are safe and effective and perform as well as or better than the predicate device, the 3.0T 8-Channel Shoulder Array Coil, K071611 cleared on 06/28/2007 for the indications claimed.