NeoCoil, LLC
Michael Leigh
Director, Regulatory Affairs
N27 W23910A Paul Rd.
Pewaukee, Wisconsin 53072

February 16, 2018

Re: K173409
Trade/Device Name: Wireless Audio System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: January 22, 2018
Received: January 24, 2018

Dear Michael Leigh:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael D. O'Hara 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173409

Device Name
NeoCoil Wireless Audio System

Indications for Use *(Describe)*
The NeoCoil Wireless Audio System is intended to provide entertainment and facilitate patient communication in MRI environments at 3 Tesla field strength and below.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

Michael Leigh
Director, Regulatory
262-347-1250 (office)
261-347-1251 (fax)
mike.leigh@neocoil.com

5.3. Preparation Date

5.4. Name of Device

- Proprietary Name: NeoCoil Wireless Audio System
- Common Name: Nuclear Magnetic Resonance System
- Classification: 21 CFR 892.1000, Product Code LNH

5.5. Model Numbers

NeoCoil Model Number	NeoCoil Model Name
NC069201	Technologist Console Interface
NC079202	Penetration Panel Transmitter
NC071200	Wireless Patient Headphones
NC075200	Wireless Audio Interface
NC107200	S1 Audio Interface Module
NC130200	S2 Audio Interface Module
NC130202	P2 Audio Interface Module
NC126200	Scan Room Module
NC126201	Wireless Router
NC126202	Technologist Console Interface

5.6. Device Description

The NeoCoil Wireless Audio System is intended to provide entertainment and facilitate communications between the patient and the operator in a Magnetic Resonance Imaging (MRI) scanner environment. The Wireless Audio System is intended to be used by healthcare professionals.

The NeoCoil Wireless Audio System is a modular system comprised of wireless patient headphones, a remote audio data source unit, and communications infrastructure.

5.7. Predicate Device

- Patient Communication and Entertainment System , K133670, as cleared on 07/24/2014

5.8. Comparison to Predicate

The NeoCoil Wireless Audio System is similar in physical, performance, design and material characteristics to the legally marketed device Patient Communication and Entertainment System, K133670, as cleared on 07/24/2014.

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

The NeoCoil Wireless Audio System includes the following differences to the predicate.

- Improved Noise Reduction Rating to 29dBA
- Optional Wireless Audio Interface for use with a head coil
- Additional installation options for wired, pneumatic, or wireless communication with the control room

Clinical testing demonstrates that use of the NeoCoil Wireless Audio System does not affect the safety and/or the effectiveness of the device when used as labeled.

5.9. Indications for Use

The NeoCoil Wireless Audio System is intended to provide entertainment and facilitate patient communication in MRI environments at 3 Tesla field strength and below.

5.10. Intended Use

The NeoCoil Wireless Audio System is intended to provide entertainment and facilitate patient communication in MRI environments. The product is not intended for medical diagnosis or treatment.

The product is intended for "MR Conditional" use in MRI environments at 3 Tesla and below. Technologist control units are intended to be used outside the MRI scan room.

Wireless receivers are intended for use outside the imaging field of view.

5.11. Testing

The following data has been submitted, referenced or relied on to demonstrate that the NeoCoil Wireless Audio System 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
Max B1 in first fault conditions	Pre-defined performance standards	**PASS:** Wireless Audio System does not arc or show any signs of voltage breakdown.
Surface Temperature in normal and first fault conditions	Pre-defined performance standards	**PASS:** RF heating is not greater than 41^{O} C.
NEMA MS 6-2008	Pre-defined performance standards	**PASS:** Wireless Audio System does not adversely impact MR image SNR and Uniformity
Coherent Noise Test	Pre-defined performance standards	**PASS:** Wireless Audio System does not introduce image artifacts noise in center frequency range of compatible field strengths.
Noise Reduction	Pre-defined performance standards	**PASS:** ≥29 dBA NRR (ANSI S3.19-1974)
Quality of Service and Coexistence Test	Pre-defined performance standards	**PASS:** Wireless Audio System provides adequate quality of service for patient communication during MRI scanning.

Published Standards Testing:

The NeoCoil Wireless Audio System has been evaluated to the following standards:

Standard	Purpose
IEC 60601-1	Electromechanical safety
IEC 60601-1-2	Electromagnetic Compatibility
IEC 60601-1-6	Usability
IEC 60601-2-33	Electromechanical safety for magnetic resonance equipment
IEC 62366	Guidance on the application of usability engineering to medical devices
ISO 10993-1	Biocompatibility
NEMA MS6	Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images

Performance Testing - Clinical:
Clinical data submitted exhibits a mix of pulse sequences and imaging options in the axial, sagittal and coronal planes 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 NeoCoil Wireless Audio System does not adversely affect MR image production in the worst-case environment.

5.12. Conclusion

This submission demonstrates that the Indications for Use associated with the NeoCoil Wireless Audio System are as safe and effective as the predicate device, Patient Communication and Entertainment System, K133670, as cleared on 07/24/2014. As such, the NeoCoil Wireless Audio System is equivalent to its predicate, Patient Communication and Entertainment System, K133670, as cleared on 07/24/2014.