June 14, 2018

MRIaudio
Joe Caruso
Chief Operations Officer
2720 Loker Ave., Suite N
CARLSBAD, CA 92010

Re: K180100
Trade/Device Name: MRIaudio PREM System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH
Dated: May 14, 2018
Received: May 21, 2018

Dear Joe Caruso:

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.

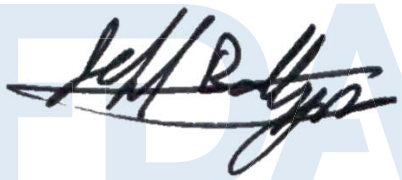
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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,



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: 06/30/2020
See PRA Statement below.

510(k) Number
K180100

Device Name

MRIaudio PREM system

Indications for Use

The MRIaudio PREM system is intended to provide audio entertainment and facilitate patient communication in MRI environments, up to, and including, 3.0 Tesla. The product is not intended for medical diagnosis or treatment. Technologist control units are intended to be used outside of the MRI scan room.

Type of Use

☉ 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.

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510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Joe Caruso
Chief Operations Officer
MRIaudio, Inc.
2720 Loker Avenue West, Suite N
Carlsbad, CA 92010
Telephone: (858) 914-4217
Date Prepared: May 14, 2018

B. Device Name

Trade or Proprietary Name:	*MRIaudio PREM System*
Classification Name:	Magnetic Resonance Diagnostic Device
Classification Regulation:	21 CFR § 892.1000
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	LNH

C. Predicate Devices

Trade or Proprietary Name:	Patient Communication and Entertainment System
Maufacturer:	NeoCoil, LLC
510(k) Clearance:	K133670
Classification Regulation:	21 CFR § 892.1000
Classification Name:	Magnetic Resonance Diagnostic Device
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	LNH

D. Device Description

The *MRIaudio PREM system* is an MRI conditional audio solution that provides MRI patients with music, direct communication, and hearing protection.

E. Indications for Use

The *MRIaudio PREM system* is intended to provide audio entertainment and facilitate patient communication in MRI environments, up to, and including, 3.0 Tesla. The product is not intended for medical diagnosis or treatment. Technologist control units are intended to be used outside of the MRI scan room.

F. Technological Characteristics

As was established in this submission, the subject *MRIaudio PREM system* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function.

G. Performance Data

Testing was performed to demonstrate that the subject *MRIaudioPREM system* is substantially equivalent to other predicate devices. The following bench and clincal testing was performed:

Test	**Result**
Noise Reduction to ANSI S3.19-1974	29 dBA NRR
Magnetic field attraction/MR Conditional rating (3-Tesla field strength)	No field interaction up to two (2) feet from bore and one (1) foot from the side of magnet

The subject *MRIaudioPREM system* has also been evaluated to the following standards:

Electrical Safety/Electromagnetic Compatibility	
IEC 60601-1	Medical electrical equipment – Part 1. General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
Biocompatibility	
ISO 10993-1	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

The results of performance testing demonstrate that the subject *MRIaudio PREM system* presents no adverse effect within the intended environment, and the subject device was therefore found to be substantially equivalent to the predicate.

Futher, 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, *Guidance for the Submission Of Promarket Notifications for Magnetic Resonance Diagnostic Devices, issued November 14, 1998*. No adverse events were reported; therefore, the subject *MRIaudioPREM system* does not adversely affect MR image production in the worst-case environment.

H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *MRIaudioPREM system* has been shown to be substantially equivalent to legally marketed predicate devices.