Innovere Medical Inc.
% Ms. Lynsie Thomason
Regulatory & Operations Lead
6-250 Shields Court
Markham, Ontario L3R 9W7
CANADA

April 7, 2020

Re: K193218
Trade/Device Name: Innovision Audio
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: March 6, 2020
Received: March 9, 2020

Dear Ms. Thomason:

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) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193218

Device Name

Innovision Audio

Indications for Use *(Describe)*

The Innovision Audio system is intended to provide entertainment and facilitate communication from the operator to the patient in the MRI scanner environment. The system is intended for "MR Conditional" use during supine MRI examinations at 1.5T and 3.0T.

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.

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SECTION 5 : 510(k) Summary

5.1 Applicant/Submitter

Company Name	:	Innovere Medical Inc.
Establishment Registration Number	:	
Phone Number	:	1-888-262-0408
Company Street Address	:	6-250 Shields Court
Fax Number	:	
City	:	Markham
State	:	ON
Country	:	Canada
Zip Code	:	L3R 9W7

5.2 Contact Person

Full Name	:	Lynsie Thomason
Job Title	:	Regulatory & Operations Lead
Phone	:	1-888-262-0408 (x104)
Email	:	lynsie.thomason@innoveremedical.com

5.3 Date of Preparation

Date of Preparation	:	12/13/2019

5.4 Device Information

Table - 5.1 Device Information

Trade Name	Innovision Audio
Common or Usual Name	Magnetic resonance diagnostic device.
Classfication Name	21 CFR 892.1000
Regulatory Class	2
Product Code	LNH

5.5 Device Description

Innovision Audio is a wireless device intended to provide entertainment and facilitate communication from the operator to the patient in the MRI scanner environment. The Innovision Audio system is intended to be used by healthcare professionals.

Innovision Audio is a multi-component system comprised of a wireless patient pillow, wireless bridges (data relays), and a Console Unit (entertainment control centre).

5.6 Predicate Device(s)

Table - 5.2 Predicate Device(s)

Predicate Type	510(k) Number	Device Name	Manufacturer
Primary Device	K173409	Wireless Audio System	NeoCoil, LLC

5.7 Comparison of Technological Characteristics with Predicate

Based on the evidence provided, the Innovision Audio System is substantially equivalent to the legally marketed device NeoCoil Wireless Audio System (K173409, cleared on 02/16/2018).

Use of the devices with the MRI scanner is similar.

The Innovision Audio system differs from the predicate in the following ways:

- Innovision Audio has a higher Noise Reduction Rating of >32dB
- Innovision Audio delivers audio to the patient through a pillow instead of traditional headphones/earbuds
- Innovision Audio includes an entertainment audio source with the device

Bench testing demonstrates that the use of the Innovision Audio system is safe and effective and does not affect the safety or effectiveness of the MRI system when used as intended.

5.8 Indications for Use

The Innovision Audio system is intended to provide entertainment and facilitate communication from the operator to the patient in the MRI scanner environment. The system is intended for "MR Conditional" use during supine MRI examinations at 1.5T and 3.0T.

5.9 Testing

The testing summarized in Table - 5.3 Performance Testing - Bench and Table - 5.4 Published Standards Testing have been submitted, referenced or relied on to demonstrate the safety and effectiveness of Innovision Audio. The device performs as intended.

Table - 5.3 Performance Testing - Bench

Test	Pass/Fail Criteria	Results
MR safety	Pre-defined performance standards	PASS RF, gradient and combined fields heating of applied parts is not greater than 41^{O}C.
NEMA MS 1 NEMA MS 2 NEMA MS 3	Pre-defined performance standards	PASS Innovision Audio has no appreiable effect on MR image quality through assessment of image SNR, signal uniformity, geometric distortion.
MR Immunity	Pre-defined performance standards	PASS Innovision Audio is immune to the fields generated during MR imaging.
Usability of device	Pre-defined performance standards	PASS Innovision Audio is usable and minimally dirsruptive to the MRI workflow.

Table - 5.4 Published Standards Testing

Standard	Purpose

IEC 60601-1	Electrical safety
IEC 60601-1-2	Electromagnetic compatiblity
ISO 10993-1	Biocompatiblity
NEMA MS 1	Signal-to-Noise Ratio (SNR) in MR images
NEMA MS 2	2-Dimensional geometric distortions in MR images
NEMA MS 3	Image uniformity of MR images

5.10 Conclusion

This submission demonstrates that for the specified indications for use the Innovision Audio system is as safe and effective as the predicate device, NeoCoil Wireless Audio System, K173406, as cleared on 02/16/2018.