Nous Imaging, Inc.
℅ Mr. Rob Newman
Regulatory Consultant
Scion Opportunity Consulting
680 Webb Road
CHADDS FORD PA 19317

August 26, 2020

Re: K201141
Trade/Device Name: FIRMM
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 3, 2020
Received: August 4, 2020

Dear Mr. Newman:

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)*

K201141

Device Name

FIRMM

Indications for Use *(Describe)*

The Nous FIRMM system is an accessory to an MRI scanner to calculate and display patient motion during a head scan. The motion results are derived from the MR image data as it is being acquired.

MR images can be imported during the scan, and analyzed to detect patient motion in real-time. FIRMM enables the operator to become aware of patient motion during the scanning session and can be used to support scanning efficiency.

The device is intended for prescription use only.

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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5 510(k) Summary

K201141

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act 1990 and 21 CFR Section 807.92.

5.1 General Information

Establishment:	Nous Imaging Inc. 4220 Duncan Ave St Louis MO 63110 Tel: +1 (314) 776-4516 Email: INFO@firmm.io Registration Number: TBD
Date Prepared:	10 Aug 2020
Manufacturer:	Nous Imaging Inc. 4220 Duncan Ave St Louis MO 63110 Phone: (314) 296-5648

5.2 Contact Information

Rob Newman
Scion Consulting, LLC
680 Webb Road
Chadds Ford, PA 19317
Phone: 484-574-9633
Email: rob.newman@firmm.io

5.3 Device Name and Classification

Device Name:	FIRMM
Trade Name:	FIRMM
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR Sec 892.1000
Classification:	Class II

Product Code:	LNH

5.4 Legally Marketed Predicate Device

Trade Name:	KinetiCor Motion Correction System
Classification Name:	Magnetic Resonance Diagnostic Device (MRDD)
Classification Panel:	Radiology
CFR Code:	21 CFR Sec 892.1000
Classification:	Class II
Product Code:	Primary: LNH

5.5 Indications For Use

The Nous FIRMM system is an accessory to an MRI scanner to calculate and display patient motion during a head scan. The motion results are derived from the MR image data as it is being acquired.

MR images can be imported during the scan, and analyzed to detect patient motion in real-time. FIRMM enables the operator to become aware of patient motion during the scanning session and can be used to support scanning efficiency.

The device is intended for prescription use only.

5.6 Device Description

Magnetic resonance imaging (MRI) has unrivaled clinical and research utility as a diagnostic imaging modality in use worldwide. However, the utility of MRI has one significant limitation: patient motion during an MRI scan can greatly diminish the diagnostic quality of the images. The result is a decision to either to repeat the scan series, or to use the images regardless of their compromised diagnostic information.

The company has developed a software-based system that performs Framewise Integrated Real-time MRI Monitoring (FIRMM®). The FIRMM system continuously monitors the MR image data as it is being generated during the exam to detect small displacements (rotation or translation) of the anatomy along any axis during MRI acquisitions of time series datasets. It quantifies these movements and provides the MRI scanner operator with a plot of patient motion displayed as type of ‘seismograph’, as well as providing a figure of overall motion quality. This system allows for non-invasive, non-contact monitoring of patient motion during brain MRIs, and displays motion metrics in real-time to the scanner operator, with an optional ability to provide biofeedback to the patient.

Real-time feedback on patient motion during the scan can be very helpful to the scan operator who, as a result may be able to better manage the study, allowing the patient and operator to complete the exam yielding diagnostic quality images with fewer motion artifacts.

The FIRMM system itself has no interaction with the data acquisition process, and there is no component of the FIRMM system inside the imaging volume. Because FIRMM only has read access to the scanner, FIRMM has no direct impact on scan time or diagnostic image generation of the MRI scanner.

Hardware

The FIRMM software is run on a dedicated off-the-shelf computer tablet with a touch screen display operating in kiosk mode. The tablet is IEC 60601-1 and IEC 60601-1-2 compliant and sits next to the MR scan operator. The FIRMM application is the only function provided by the system. The computer is strictly an appliance and the user cannot alter its function outside of the provided administration and configuration functions accessed from the touch screen.

The system includes a video output with a HDMI signal that can be connected to an in-bore entertainment system (customer supplied item) and can also provide a biofeedback display to the patient of any detected motion. This system may be helpful to make patients aware of small voluntary motions.

5.7 Risk Management, General Safety and Effectiveness

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by design means, protection measures and user instructions. To confirm that the measures are effective and that the product meets its intended uses, verification of requirements and standards, and validation of the clinical workflow was performed. Nous Imaging adheres to recognized and established industry practice and relevant international standards where indicated.

5.8 Technological Characteristics and Substantial Equivalence

Nous FIRMM System is substantially equivalent to the predicate device; both systems have the fundamental purpose of detecting and reducing the effects of patient motion on MR exams. FIRMM has the same intended use, and similar indications, technological characteristics and principles of operation as its predicate device.

While the predicate device tracks patient motion via a fiducial/tracking camera, the FIRMM system uses the MR images as they are being produced. FIRMM provides feedback on patient motion to the scan operator during the MRI scans, whereas the predicate provides direct viewing of the patient's face was well a view of the raw motion

traces from the tracking system on an optional monitor. Additionally, the predicate provides the patient motion correction coordinates to the MRI scan, to actively adjust the MR image acquisitions minimize the effects of motion in the images. The technological differences between the FIRMM and its predicate devices raise no new issues of safety or effectiveness. Therefore, the technological characteristics, and principles of operation are substantially equivalent to the predicate device.

5.9 Nonclinical Tests

- Software Verification and Validation testing was performed in accordance with the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", dated May 11, 2005 and with Design Control Regulations (21 CFR 820).
- Electrical Safety: The tablet hardware was certified by the OEM manufacturer to the general standard IEC 60601-1 "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance". Certification is included which shows that the tablet hardware is in compliance with IEC 60601-1.
- Electromagnetic Compatibility: The tablet hardware was tested to 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". Certification is included which shows that the tablet hardware is in compliance with IEC 60601-1-2.
- Accuracy: An accuracy study was conducted using a synthetic data set that included known frame displacement (FD) values. The data set was processed by the FIRMM system and the resulting FD values were compared to the known FD values. The conclusion is that the accuracy exceeds the specification.
- Compatibility: Evidence of compatibility with the scanner, projection systems, and screen resolutions was based upon a combination of studies:
    - Scanner and fMRI Compatibility Study
    - Biofeedback Compatibility Study
    - Screen Resolution Compatibility Study
- 4dfp comparison study: A wide variety of data sets from adult and infant subjects were processed by FIRMM as well as a reference off-line method. The results showed the that FIRMM correlates very strongly with the reference method.

The nonclinical data support the safety of the device and the hardware and software verification and validation demonstrate that the FIRMM system should perform as intended in the specified use conditions.

5.10 Conclusions

The Nous FIRMM System is substantially equivalent to the predicate device; both systems have the fundamental purpose of detecting and reducing the negative effects of patient motion on MR exams. FIRMM has the same intended uses and similar indications, and principles of operation as its predicate device. While the predicate uses a camera/fiducial system in the bore of the magnet and direct video observation of the patient, and FIRMM uses the MR images as they are being produced, the technological differences between the FIRMM and its predicate devices raise no new issues of safety or effectiveness.

Nous believes that FIRMM as an accessory to a medical device is substantially equivalent to the currently marketed device KinetiCor's Motion Correction System. The subject device does not raise any new questions with respect to safety or effectiveness. The conclusions drawn from the nonclinical tests demonstrate that the device is safe, and effective.