Hyperfine Research, Inc.
℅ Robert Fasciano, Ph.D.
Head of Quality Assurance and Regulatory Affairs
530 Old Whitfield Street
GUILFORD CT 06437

August 11, 2020

Re: K201722
Trade/Device Name: Hyperfine Point-Of-Care Magnetic Resonance Imaging Scanner System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: June 19, 2020
Received: June 23, 2020

Dear Dr. Fasciano:

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)*

K201722

Device Name

Point-of-Care Magnetic Resonance Imaging Scanner System

Indications for Use *(Describe)*

The Point-of-Care Magnetic Resonance Imaging Device is a bedside magnetic resonance imaging device for producing images that display the internal structure of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

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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HYPERFINE
530 Old Whitfield Street, Guilford, CT 06437 (203) 204-6900

510(k) Summary of Safety and Effectiveness

Submitter Information

Submitter Name and Address
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Head of Quality Assurance and Regulatory Affairs
617-425-9098 (cell)
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Date Prepared
June 19, 2020

Subject Device - Proprietary/Trade Name
Point-of-Care Magnetic Resonance Imaging Scanner System

Subject Device - Common Name
Magnetic Resonance Imaging (MRI)

Classification Name	Regulation Number	Product Code
System, Nuclear Magnetic Resonance Imaging	892.1000	90-LNH
Coil, Magnetic Resonance, Specialty	892.1000	90-MOS

Classification
Class II

Predicate Device:
K192002 – Lucy Point-of-Care Magnetic Resonance Imaging Device, Hyperfine Research, Inc.

Device Summary:
The Point-Of-Care Magnetic Resonance Imaging (POC MRI) system is an MRI device that is portable allowing patient bedside imaging. It enables visualization of the internal structures of the head using standard magnetic resonance imaging contrasts. The main interface is a commercial off-the-shelf device, used to operate the system, provide access to patient data, exam set-up, exam execution, and MRI image data viewing for quality control purposes as well as for cloud storage interactions. The POC MRI system can generate MRI data sets with a broad range of contrasts.

The user interface includes touch screen menus, controls, indicators and navigation icons that allow the operator to control the system and to view imagery.

Indications for Use:
The Point-of-Care Magnetic Resonance Imaging Device is a bedside magnetic resonance imaging device for producing images that display the internal structure of the head where full diagnostic examination is not clinically practical. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.

Summary of Technological Characteristics
There are no technological characteristics, features or indications for use in this submission that are not previously evaluated and cleared in the predicate device. The technology meets the same intended use and performs the same actions.

Summary of Safety and Performance
Verification and validation activities were designed and performed to demonstrate that the POC MRI meets predetermined performance specifications. The following standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

ANSI AAMI 60601-1: 2005 (+ Amendment 1) Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-2-33: Edition 3.2 - 2015, Medical Electrical Equipment - Part 2-33: Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis
IEC 60601-1-2: Edition 4.0 - 2014, Medical Electrical Equipment- Part 1-2:

General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 60601-1-6: Edition 3.1 - 2013, Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
ISO 10993-1: Edition 5 - 2018 Biological Evaluation of Medical Devices. Part 1
ISO 14971: 2007 (R)2010 Application of Risk Management to Medical Devices
IEC 62304: 2006 (+ Amendment 1) Medical Device Software – Software Lifecycle Process
NEMA MS 1-2008 (R2014) Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging
NEMA MS 3-2008 (R2014) Determination of Image Uniformity in Diagnostic Magnetic Resonance Images
NEMA MS 8-2008 Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems
NEMA MS 9-2008 (R2014) Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images
NEMA MS 12-2016 Quantification and Mapping of Geometric Distortion for Special Applications

Summary of Substantial Equivalence:
Based on the indications for use, technological characteristics, and safety and performance testing, the subject device meets the requirements that are considered adequate for its intended use and is substantially equivalent in design, principles of operation and indications for use to the predicate device.