February 6, 2020

Hyperfine Research, Inc.
% Mr. Brian Sawin
Sr. Regulatory Affairs Manager
530 Old Whitfield Street
GUILFORD CT 06437

Re: K192002
Trade/Device Name: Lucy Point-of-Care Magnetic Resonance Imaging Device
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH
Dated: January 7, 2020
Received: January 9, 2020

Dear Mr. Sawin:

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,

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)*

K192002

Device Name

Lucy Point-of-Care Magnetic Resonance Imaging Device

Indications for Use *(Describe)*

The Lucy 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.

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HYPERFINE
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510(k) Summary of Safety and Effectiveness K192002

Submitter Information

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Date Prepared
February 6, 2020

Subject Device - Proprietary/Trade Name
The Lucy Point-of-Care Magnetic Resonance Imaging Device

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:
K170978 – Embrace Neonatal MRI System, Aspect Imaging Ltd.

Device Summary:
Lucy is a magnetic resonance imaging (MRI) device. Its portability allows 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. Lucy 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 Lucy 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.

Comparison of Specifications:

Comparison of Specifications	Embrace Neonatal MRI System (K170978)	Lucy Point-of Care Magnetic Resonance Imaging device
Intended Use/Indications for Use	The Embrace Neonatal MRI System is indicated for use as a magnetic resonance imaging device for producing axial, sagittal, coronal and oblique images that displays the internal structure of neonatal head with a circumference of up to 38 cm and weight between 1Kg and 4.5 Kg. When interpreted by a trained physician, these images provide information that can be useful in determining a diagnosis.	The Lucy 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.
Patient Population	Patients requiring MR images of the Neonatal Head	Adult and pediatric patients (above 2 years old)
Anatomical Sites	Neonatal Head	Head

Environment of Use	Hospital setting	At the point of care in medical facilities including emergency rooms, critical care units, hospital or rehabilitation rooms.
Energy Used and/or delivered	Magnetic Resonance	Magnetic Resonance
Human Factors	The Embrace Neonatal MRI System is designed similar to other commercially available MRI Systems and therefore is familiar and easy for use for the user. Furthermore, the device contains a user-friendly software interface through which the user may easily access all device functions.	Lucy is designed similar to other commercially available MRI Systems and therefore is familiar and easy to use for the user. Furthermore, the device contains a user-friendly software interface through which the user may easily access all device functions
Magnet:		
Physical Dimensions	1710 mm x 1450 mm x 1810 mm	835 mm x 630 mm x 652 mm
Bore Opening	180 x 260 mm	610 mm x 315 mm
Weight	5500 (5680 with bed) Kg	320 kg
Field Strength	1 Tesla permanent magnet	64 mT permanent magnet
Gradient:		
Strength	150 mT/m	16 mT/m
Rise Time	0.3 mSec	0.5 ms
Slew Rate	500 T/m/Sec	28 T/m/s
Computer:		
Display	24” LED Display	User supplied tablet
RF Coils:	1 Head Coil	1 Head Coil
Coil Type	TX/RX	TX/RX
Coil Geometry	Cylindrical	Form-fitting
Inner Dimensions (mm)	143mm Diameter	205 mm x 240 mm
Coil Design	Linear Volume	Linear Volume
Target Population	Neonates with head circumference of up to 38 cm and weight between 1Kg and 4.5 Kg	Adult and pediatric patients (above 2 years old)
Patient bed dimensions	60.6cm W x 120cm H x 140cm L	n/a

Patient Weight Capacity	4.5 Kg Max	200 kg
Operation Temperature	20.5C - 36.5C	18-25 C
Warm Up Time	50 minutes	3 minutes
Temperature Control	Air	No
Humidity Control	No	No

Summary of Technological Characteristics
The Lucy Point-of-Care Magnetic Resonance Imaging Device has different technological characteristics from the predicate, including field strength and portability; however, 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 Lucy Point-of-Care Magnetic Resonance Imaging Device meets pre-determined performance specifications. Clinical images were provided and demonstrate adequate diagnostic quality for the intended use. The following standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device:

IEC 60601-1:2005, MOD. Medical Electrical Equipment - Part 1: General Requirements for Safety
IEC 60601-2-33: Edition 2.0 - 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 10993:2009 Biological Evaluation of Medical Devices. Part 1
ISO 14971: 2012 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 3-200 (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 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.