Hyperfine, Inc.
% Ms. Christine Kupchick
Sr. Regulatory Specialist
530 Old Whitfield Street
Guilford, Connecticut 06437

July 7, 2021

Re: K211818
Trade/Device Name: Swoop™ Point-of-Care Magnetic Resonance Imaging (POC MRI) Scanner System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: June 10, 2021
Received: June 11, 2021

Dear Ms. Kupchick:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211818

Device Name
Swoop™ Point-of-Care Magnetic Resonance Imaging (POC MRI) Scanner System

Indications for Use *(Describe)*
The Swoop 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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510(k) SUMMARY
K211818

510(k) Submitter

Company Name: Hyperfine, Inc.
Company Address: 530 Old Whitfield St
Guilford, CT 06437

Contact

Name: Christine Kupchick
Telephone: (203) 343-3404
Fax: (203) 458-2514
Email: ckupchick@hyperfine.io

Date Prepared: July 2, 2021

Device Identification

Trade Name: Swoop™ Point-of-Care Magnetic Resonance Imaging (POC MRI) Scanner System
Common Name: Magnetic Resonance Imaging
Regulation Number: 21 CFR 892.1000
Classification Name: System, Nuclear Magnetic Resonance Imaging
Coil, Magnetic Resonance, Specialty
Product Code: LNH; MOS
Regulatory Class: Class II

Predicate Device Information

The subject Swoop POC MRI Scanner System is substantially equivalent to the predicate POC MRI Scanner System (K201722).

The predicate device has not been subject to a design-related recall.

Device Description

The Swoop POC MRI Scanner System is a portable MRI device that allows for patient bedside imaging. The system 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 that is used for operating the system, providing access to patient data, exam setup, exam execution, viewing MRI image data for quality control purposes, and cloud storage interactions. The system can generate MRI data sets with a broad range of contrasts. The Swoop POC MRI Scanner System user interface includes touchscreen menus, controls, indicators and navigation icons that allow the operator to control the system and to view imagery.

The purpose of this submission is to gain clearance for updates to the software to include automatic alignment and motion correction features.

Indications for Use

The Swoop 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.

Substantial Equivalence Discussion

The table below compares the subject device to the predicate.

Specification	Subject Swoop Portable MRI Device	Predicate POC MRI Device (K201722)
Indications for Use	The Swoop 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.	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.
Patient Population	Adult and pediatric (≥ 0 years)	Adult and pediatric (≥ 0 years)
Anatomical Site	Head	Head
Patient Weight Capacity	200 kg	200 kg
Energy Type	Magnetic Resonance	Magnetic Resonance
Operation Temperature	15-30C	15-30C
Warm Up Time	<3 min	<3 min
MAGNET		
Physical Dimensions	835 mm x 630 mm x 652 mm	835 mm x 630 mm x 652 mm
Bore Opening	610 mm x 315 mm	610 mm x 315 mm
Weight	320 kg	320 kg
Field Strength	63.3 mT permanent magnet	63.3 mT permanent magnet
GRADIENT		
Strength	24 mT/m	24 mT/m
Rise Time	0.4 ms	0.4 ms
Slew Rate	22 T/m/s permanent magnet	22 T/m/s permanent magnet
COMPUTER		
Display	User supplied tablet	User supplied tablet
RF COIL		
RF Coils	1 Head Coil	1 Head Coil
Coil Type	TX/RX	TX/RX
Coil Geometry	Form-Fitting	Form-Fitting

Inner Dimensions	205 mm x 240 mm	205 mm x 240 mm
Coil Design	Linear Volume	Linear Volume

The subject device and the predicate device have the same intended use, operating principles and similar technological characteristics. The subject device differs from the predicate in software features, which include automatic alignment and motion correction. Additionally, minor changes were made through letter-to-file to both the software and hardware of the device. The minor changes to the software included updates to the user interface and enhanced security features, and the minor changes to the hardware included modifications to the RF shield and screen, gauss guard, and battery charger through. These differences do not raise new questions of safety and effectiveness as compared to the predicate.

NON-CLINICAL PERFORMANCE

The subject device has similar technological characteristics as the predicate (K201722) and differs only in software, which includes automatic alignment and motion correction features, updates to the user interface, and enhanced security features. As part of demonstrating substantial equivalence to the predicate, a risk analysis was completed to identify the risks associated with the software modifications. Performance testing was conducted to evaluate the modifications. The subject device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence.

- **Software Verification** per IEC 62304:2006 and as recommended in the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"

- **Cybersecurity Information** provided as recommended in FDA Guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"

The following testing was leveraged from the predicate device (K201722). Test results from the predicate were used to support the subject device because the conditions were identical or the subject device modifications did not introduce a new worst-case configuration or scenario for testing.

- **Biocompatibility** per ISO 10993-1:2018

- **Electrical Safety, EMC and Essential Performance** per ANSI/AAMI ES 60601-1:2005/(R)2012, IEC 60601-2-33:2015, and IEC 60601-1-2:2014

- **Electrical Safety Collateral Standard: Usability** per IEC 60601-1-6:2013

- **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 8-2016** - 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

CONCLUSION

The results of the testing described above demonstrate that the subject Swoop POC MRI Scanner System is as safe and effective as the predicate and supports a determination of substantial equivalence.