June 10, 2022

Hyperfine, Inc.
% Christine Kupchick
Sr. Regulatory Specialist
351 New Whitfield Street
GUILFORD CT 06437

Re: K221393
Trade/Device Name: Swoop® Portable MR Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: May 23, 2022
Received: May 24, 2022

Dear Christine 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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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)*
K221393

Device Name
Swoop® Portable MR Imaging System

Indications for Use *(Describe)*
The Swoop® Portable MR Imaging System 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
Swoop® Portable MR Imaging System
K221393

510(K) SUBMITTER

Company Name: Hyperfine, Inc.
Company Address: 351 New Whitfield St
Guilford, CT 06437

CONTACT

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

Date Prepared: June 10, 2022

DEVICE IDENTIFICATION

Trade Name: Swoop® Portable MR Imaging 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® Portable MR Imaging System is substantially equivalent to the predicate Swoop® System (K212456).

DEVICE DESCRIPTION

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

System image reconstruction algorithm utilizes deep learning to provide improved image quality for T1W, T2W, and FLAIR sequences, specifically in terms of reductions in image noise and blurring.

This subject device in this submission includes modified pulse sequence options and an enhancement to the existing noise correction feature to remove residual line noise.

INDICATIONS FOR USE

The Swoop® Portable MR Imaging System 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® System	Predicate Swoop® System (K212456)
Intended Use/Indications for Use:	The Swoop® Portable MR Imaging System 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.	Same
Patient Population:	Adult and pediatric patients (≥ 0 years)	Same
Anatomical Sites:	Head	Same
Environment of Use:	At the point of care in medical facilities, including emergency rooms, critical care units, hospital or rehabilitation rooms.	Same
Energy Used and/or delivered:	Magnetic Resonance	Same
Magnet:		
Physical Dimensions	835 mm x 630 mm x 652 mm	Same
Bore Opening	610 mm x 315 mm	Same
Weight	320 kg	Same
Field Strength	63.3 mT permanent magnet	Same
Gradient:		
Strength	24 mT/m	Same
Rise Time	1.1 ms	Same
Slew Rate	22 T/m/s	Same
Computer Display	Hyperfine-supplied tablet	Same
RF Coils:		
Number of Coils	1 head coil	Same
Coil Type	TX/RX	Same
Coil Geometry	Form-fitting	Same

Specification	Subject Swoop® System	Predicate Swoop® System (K212456)
Inner Dimensions (mm)	205 mm x 240 mm	Same
Coil Design	Linear Volume	Same
Patient Weight Capacity	200 kg	Same
Operation Temperature	15-30 C	Same
Warm Up Time	<3 minutes	Same
Temperature Control	No	Same
Humidity Control	No	Same
Image Reconstruction Algorithm		
T1W - T1-Standard - T1-Gray/White Contrast	Advanced Gridding	Advanced Gridding (T1-Gray/White Contrast only)
T2W - T2 - T2-Fast	Advanced Gridding	Advanced Gridding (T2 only)
FLAIR	Advanced Gridding	Same
DWI	Conjugate Gradient	Same
Image Post-Processing	- Advanced Denoising (applies to T1W, T2W, and FLAIR only) - Image orientation transform - Geometric distortion correction - Receive coil intensity correction - DICOM output	Same

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 pulse sequence options and noise correction. These differences do not raise new questions of safety and effectiveness as compared to the predicate.

NON-CLINICAL PERFORMANCE

As part of demonstrating substantial equivalence to the predicate, a risk-based assessment was completed to identify the risks associated with the modifications. Based on the risk assessment, the following verification and validation testing was performed. The subject device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence.

Test	Test Description	Applicable Standard(s)
Software Verification	Testing to verify that the advanced reconstruction models do not alter image features or introduce artifacts.	● IEC 62304:2006 ● FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
	Testing to verify that image quality with advanced reconstruction is acceptable.	
	Testing to verify basic software functionality is unchanged between releases.	
	NESSUS scan test to verify any vulnerabilities and serve as a security baseline.	

Image Performance	Testing to verify image performance with advanced reconstruction meets all image quality criteria.	• NEMA MS 1-2008 (R2020) • NEMA MS 3-2008 (R2020) • NEMA MS 9-2008 (R2020) • NEMA MS 12-2016 • American College of Radiology (ACR) Phantom Test Guidance for Use of the Large MRI Phantom for the ACR MRI Accreditation Program • American College of Radiology standards for named sequences
Software Validation	Validation studies to ensure the device meets user needs and performs as intended.	• FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
Cybersecurity	Testing to verify cybersecurity controls and management.	• Cybersecurity 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. 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.

Test	Test Description	Applicable Standard(s)
Biocompatibility	Biocompatibility testing of patient-contacting materials.	• ISO 10993-1:2018 • ISO 10993-5:2009 • ISO 10993-10:2010
Cleaning/ Disinfection	Cleaning and disinfection validation of patient-contacting materials.	• FDA Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" • ISO 17664:2017 • ASTM F3208-17
Safety	Electrical Safety, EMC, and Essential Performance testing.	• ANSI/AAMI ES 60601-1:2005/(R)2012 • IEC 60601-1-2:2014 • IEC 60601-1-6:2013
Performance	Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems.	• NEMA MS 8-2016

CONCLUSION

Based on the indications for use, technological characteristics, performance results, and comparison to the predicate, the subject Swoop® Portable MR Imaging System has been shown to be substantially equivalent to the predicate device identified in this submission and does not present any new issues of safety or effectiveness.