



October 6, 2023

Hyperfine, Inc.
% Christine Kupchick
Staff Regulatory Affairs Specialist
351 New Whitfield Street
Guilford, CT 06437

Re: K232760

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: September 8, 2023
Received: September 8, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink, appearing to read 'DK', is written over a faint, light blue background watermark that says 'FDA'.

Daniel M. Krainak, Ph.D.
Assistant 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

Indications for Use

510(k) Number (if known)

K232760

Device Name

Swoop® Portable MR Imaging System®

Indications for Use (Describe)

The Swoop Portable MR Imaging System is a portable, ultra-low field 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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510(k) Summary

Swoop® Portable MR Imaging System®

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: September 8, 2023

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 (K230208).

DEVICE DESCRIPTION

The Swoop system is portable, ultra-low field MRI device that 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.

The subject Swoop System described in this submission includes software modifications related to the following:

- Pulse sequence parameters (T1, T2, FLAIR, DWI)
- Image reconstruction (T1, T2, FLAIR)
- DWI image post-processing

INDICATIONS FOR USE

The Swoop Portable MR Imaging System is a portable, ultra-low field 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 MR Imaging System	Predicate Swoop Portable MR Imaging System (K230208)
Intended Use/ Indications for Use:	The Swoop Portable MR Imaging System is a portable, ultra-low field 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 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.
Patient Population:	Adult and pediatric patients (≥ 0 years)	Same
Anatomical Sites:	Head	Same
Environment of Use:	At the point of care in professional health care facilities such as 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	X: 24 mT/m, Y: 23 mT/m, Z: 39 mT/m	Same
Rise Time	X: 2.1 ms, Y: 2.0 ms, Z: 3.8 ms	Same
Slew Rate	X: 24 T/m/s, Y: 22 T/m/s, Z: 21 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
Inner Dimensions (mm)	205 mm x 240 mm	Same
Coil Design	Linear Volume	Same
Patient Weight Capacity	1.6kg-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:		
Noise Correction	Noise correction and line noise suppression for all sequences	Same
T1W - T1-Standard - T1-Gray/White Contrast	Advanced Gridding	Same
T2W - T2 - T2-Fast	Advanced Gridding	Same
FLAIR	Advanced Gridding	Same
DWI	Fast Iterative Shrinkage Thresholding Algorithm (FISTA)	Same
Image Post-Processing	- Advanced Denoising (applies to T1W, T2W, FLAIR and DWI) - Image orientation transform - Geometric distortion correction - Receive coil intensity correction - DICOM output	- Advanced Denoising (applies to T1W, T2W, and FLAIR only) - Image orientation transform - Geometric distortion correction - Receive coil intensity correction - DICOM output

The subject device and the predicate device have the same intended use, operating principles, and similar technological characteristics. There are minor differences between the subject device and the predicate in pulse sequences, image reconstruction, DWI image post-processing, and indications for use. These differences do not raise new questions of safety and efficacy 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	Software verification testing in accordance with the design requirements to ensure that the software requirements were met.	• IEC 62304:2015 • FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
Image Performance	Testing to verify the subject device 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 to ensure the subject device meets user needs and performs as intended.	• FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained 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
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"

CONCLUSION

Based on the intended 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.