May 30, 2025

Hyperfine, Inc.
Christine Kupchick
Sr. Manager, Global Regulatory
351 New Whitfield St
Guilford, Connecticut 06437

Re: K250236
Trade/Device Name: Swoop® Portable MR Imaging® System (V2)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: LNH, MOS
Dated: May 7, 2025
Received: May 7, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250236

Device Name

Swoop® Portable MR Imaging® System (V2)

Indications for Use *(Describe)*

The Swoop® Portable MR Imaging® System (V2) 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 (V2)
K250236

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: May 22, 2025

DEVICE IDENTIFICATION

Trade Name: Swoop® Portable MR Imaging® System (V2)
Common Name: Magnetic Resonance Imaging
Regulation Number: 21 CFR 892.1000
Classification Name: System, Nuclear Magnetic Resonance Imaging Coil, Magnetic Resonance
Product Code: LNH; MOS
Regulatory Class: Class II

PREDICATE DEVICE INFORMATION

The subject Swoop Portable MR Imaging System (V2) is substantially equivalent to the predicate Swoop System (K240944).

Device Description

The Swoop System (V2) 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 scan orders, exam setup, exam execution, viewing MRI image data for quality control purposes, and PACS 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 preview images. The Swoop System (V2) image reconstruction algorithm utilizes deep learning for optimized image quality.

Indications for Use

The Swoop Portable MR Imaging System (V2) 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 (V2)	Predicate Swoop Portable MR Imaging System (V1) (K240944)
INTENDED USE		
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.	Same
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, intensive/critical care units, hospitals, outpatient, or rehabilitation centers.	Same
Energy Used and/or delivered	Magnetic Resonance	Same

MAGNET		
Field strength	64.9 mT (nominal)	63.3 ± 2.0 mT
Type	Permanent magnet	Same
Patient accessible bore size	36.0 in. width, 13.4 in. height	24.0 in. width, 12.4 in. height
Magnet weight	712 lbs.	705 lbs.
GRADIENT SYSTEM		
Maximum gradient amplitude	X: 33.9 mT/m Y: 33.2 mT/m Z: 66.2 mT/m	X: 24.3 mT/m Y: 22.9 mT/m Z: 38.5 mT/m
Rise time (zero to max)	X: 1.8 ms Y: 1.8 ms Z: 5.1 ms	X: 2.1 ms Y: 2.0 ms Z: 3.8 ms
Slew rate	X: 18.8 T/m/s Y: 18.4 T/m/s Z: 13.0 T/m/s	X: 24 T/m/s Y: 22 T/m/s Z: 21 T/m/s
RF COIL		
Type	Transmit/receive	Same
Transmit coil design	Linear	Same
OTHER		
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
SEQUENCES & IMAGE PROCESSING		
T1W sequences	• T1 (Standard), T1 (Gray/White) • Advanced Gridding reconstruction	• Same • Same
T2W sequences	• T2, T2 (Fast) • Advanced Gridding reconstruction	• Same • Same
FLAIR sequences	• FLAIR, FLAIR (Fast) • Advanced Gridding reconstruction	• FLAIR only • Same
DWI/ADC sequences	• DWI/ADC, DWI/ADC (Fast) • Advanced Gridding + FISTA	• DWI/ADC only • FISTA only
Image post-processing (All Sequences)	• Advanced Denoising • Image orientation transform • Geometric distortion correction • Receive coil intensity correction • Advanced Interpolation • DICOM output	• Same • Same • Same • Same • n/a • 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 hardware and software. These differences do not raise new questions of safety and efficacy as compared to the predicate.

NON-CLINICAL PERFORMANCE

The subject device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence to the predicate.

Test	Test Description	Applicable Standard(s)
Verification	Verification testing in accordance with the design requirements.	• IEC 62304:2015 • FDA Guidance, "Content of Premarket Submissions for Device Software Functions" • NEMA MS 1-2008 (R2020) • NEMA MS 3-2008 (R2020) • NEMA MS 9-2008 (R2020) • NEMA MS 12-2016 • NEMA MS 8-2016 • 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 • FDA Guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"
Validation	Validation to ensure the subject device meets user needs and performs as intended.	• FDA Guidance, "Content of Premarket Submissions for Device Software Functions" • FDA Guidance, "Applying Human Factors and Usability Engineering to Medical Devices • IEC 62366-1:2015+AMD1:2020
Biocompatibility	Biocompatibility evaluation of patient-contacting materials.	• ISO 10993-1:2018 • ISO 10993-5:2009 • ISO 10993-10:2021 • ISO 10993-23:2021
Reprocessing	Cleaning and disinfection evaluation of patient-contacting materials.	• FDA Guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" • ISO 17664:2021 • ASTM F3208-20 • AAMI TIR12:2020 • ANSI/AAMI ST98:2022

Test	Test Description	Applicable Standard(s)
Safety	Electrical Safety, EMC, and Essential Performance testing.	• IEC 60601-1:2005 Ed.3+A1; A2 • IEC 60601-1-2:2014 Ed.4+A1 • IEC 60601-1-6:2010 Ed.3+A1; A2 • IEC 60601-2-33:2015 Ed. 3.2

ADVANCED RECONSTRUCTION PERFORMANCE ANALYSIS AND VALIDATION

Performance analysis and validation of the subject device Advanced Reconstruction models was performed using a test dataset entirely independent from the dataset used for model training. The test dataset comprises a total of 58 individual subjects and 313 unique images collected using sequence types available on the subject device. For each subject, a subset of the following sequences, chosen appropriately for the indication for imaging, was scanned: T1 Gray-White, T1 Standard, T2, T2 Fast, FLAIR, FLAIR Fast, DWI, DWI Fast (DWI b=0, b=900, ADC). Axial, Sagittal, and Coronal orientations were included; for DWI sequences, only Axial was available. A description of the acceptance criteria and subset of data used for each test is included in the test summaries below.

In all cases, models are trained and validated with MRI data and images as the only inputs and outputs; there are no confounding factors and clinical subgroups are not defined or considered. While gender and age are available for most subjects, age, gender, ethnic background, and pathology are not expected to influence model architecture.

Performance Analysis:

Study Design:
Advanced Reconstruction was assessed for robustness, stability, and generalizability over a variety of subjects, design parameters, artifacts, and scan conditions using reference-based metrics.

A set of images including Swoop data, high field images, and synthetic contrast images, was used as ground truth target images. Test input data (synthetic k-space generated from the target images) was reconstructed using both Advanced and Linear Reconstruction, and the similarity to the original ground truth image was compared between the two reconstruction methods. Reconstruction outputs with motion and zipper artifacts were qualitatively assessed.

Reference Standard and Metrics:
Normalized mean squared error (NMSE) and structural similarity index (SSIM) were used to compare the ability of Advanced Reconstruction to reproduce the ground truth image compared to Linear Reconstruction.

Dataset and Sample Size per Model:

Model/Sequence group: **T1, T2, FLAIR**		
Patients	40	
Images	111	
Demographics		
Gender	Female	38%
	Male	55%
	Unknown	7%
Age	18-35	5%
	35-60	28%
	60+	62%
	2+*	5%
Ethnicity Data	Not Recorded	
Number of sites	4	
Equipment Type	Swoop v2†	
Pathology	Atrophy, Cerebellar Infarct, Chronic Infarct, Demyelinating diseases, Embolic Infarct, Hydrocephalus, Infarct, Intracerebral Hemorrhage, Intraparenchymal Hemorrhage, Lesion, M1 Occlusion, Mass Effect, Seizure, Stroke, Subdural Hemorrhage, Traumatic Brain Injury, Tumor, White Matter Disease, White Matter Lesion	

* Partially anonymized
† Contained Swoop Mk1.9 (<1%)

Model/Sequence group: **DWI**		
# of patient	29	
# Images	94	
Demographics		
Gender	Female	35%
	Male	55%
	Unknown	10%
Age	18-35	7%
	35-60	21%
	60+	65%
	2+*	7%
Ethnicity Data	Not Recorded	
Number of sites	4	
Equipment Type	Swoop v2	
Pathology	Atrophy, Cerebella Infarct, Chronic Infarct, Demyelinating Diseases, Embolic Infarct, Infarct, Intracerebral Hemorrhage, Intraparenchymal Hemorrhage, Lesion, M1 Occlusion, Mass Effect, Stroke, Subdural Hemorrhage, Traumatic Brain Injury, Tumor, White Matter Disease	

* Partially anonymized

Study Results:

For all models and all test datasets NMSE was reduced and SSIM was improved for Advanced Reconstruction test images compared to Linear Reconstruction test images. Advanced Reconstruction preserved the presentation of motion and zipper artifacts, and no unexpected output was observed.

Contrast-to-Noise Ratio Validation

Study Design:

Regions of interest (ROI) encompassing pathologies were annotated and reviewed by two American Board of Radiology (ABR) certified radiologists. The contrast-to-noise of hyper- and hypo- intense pathologies were measured with respect to healthy white matter tissue from the same image. The inclusion criterion for images used for this study was at least one visible pathology.

Reference Standard and Metrics:

Linear Reconstruction was used as the reference standard for the comparison. Contrast-to-Noise Ratio (CNR) between pathology and healthy tissues was measured to quantify how accurately pathology features are preserved by Advanced Reconstruction.

The mean CNR of Advanced Reconstruction was required to be greater than the mean CNR of the baseline Linear Reconstruction at statistical significance level of 0.05 for each sequence type.

Dataset and Sample Size:

A minimum of 16 images per model type (sequence group) were included for lesion annotation. Pathologies spanning multiple slices were used multiple times. All annotated images were then reviewed, and inaccurate ROI annotations were excluded from the analysis. The data meeting inclusion criteria are described below.

Patients	15	
Images	46	
Pathologies	58	
ROIs	464	
Demographics and other Variability		
Gender	Female	28%
	Male	70%
	Unknown	2%
Age	35-60	28%
	60+	70%
	2+*	2%
Ethnicity Data	Not Recorded	
Number of sites	2	
Equipment	Swoop v2	
Pathology	Atrophy, Demyelinating diseases, Embolic Infarct, Infarct, Intracereberal Hemorrhage, Intraparenchymal Hemorrhage, Lesion, Resection, Stroke, Thrombectomy, Tumor, White Matter Disease, White Matter Hyperintensity, White Matter Lesion	

*Partially anonymized

Study Results:

In all cases, CNR of Advanced Reconstruction was greater than or equal to Linear Reconstruction for both hyper- and hypo-intense pathologies. The study result demonstrates that Advanced Reconstruction does not unexpectedly modify, remove, or reduce the contrast of pathology features.

Advanced Reconstruction Image Validation

Study Design:

Five external, ABR-certified radiologists representing clinical users were asked to review side-by-side clinical image sets taken with the subject Swoop System, reconstructed with both Advanced and Linear Reconstruction. The reviewers rated the images using a five-point scale for image quality and the consistency of diagnosis using both methods in the categories of noise, sharpness, contrast, geometric fidelity, artifact, and overall image quality.

Reference Standard and Metrics:

Linear Reconstruction was used as the reference standard for the comparison. Advanced Reconstruction was required to perform at least as well as Linear Reconstruction in all categories (median score ≥0 on Likert scale) and perform better (≥1 on Likert scale) in at least one of the quality-based categories.

Dataset and Sample Size:

A sample size of at least 16 was used per sequence. Within the sample dataset at least four cases for each sequence-available image orientation (axial, sagittal, coronal) were used.

Patients	32	
Images	167	
Demographics and other Variability		
Gender	Female	28%
	Male	70%
	Unknown	2%
Age	18-35	1%
	35-60	25%
	60+	35%
	2+*	39%
Ethnicity Data	Not Recorded	
Number of sites	3	
Equipment	Swoop v2	
Pathology	Included pathology: Atrophy, Chronic Infarct, Demyelinating diseases, Embolic Infarct, Hemorrhage, Hydrocephalus, Infarct, Intracereberal Hemorrhage, Intraparenchymal Hemorrhage, Lesion, M1 Occlusion, Mass Effect, Stroke, Subdural Hemorrhage, Traumatic Brain Injury, Tumor, White Matter Disease	

*Partially anonymized

Test Results:

Advanced Reconstruction achieved a median score of 2 (the most positive rating scale value) in all categories. This scoring indicates reviewers found Advanced Reconstruction improved image quality while maintaining diagnostic consistency relative to Linear Reconstruction.

CONCLUSION

Based on the intended use, technological characteristics, performance results, and comparison to the predicate, the subject Swoop Portable MR Imaging System (V2) has been shown to be substantially equivalent to the predicate and there are no new questions of safety and effectiveness.