December 12, 2025

Hyperfine, Inc.
Kristen Evenson
Sr. Manager, Regulatory Affairs
351 New Whitfield St
Guilford, Connecticut 06437

Re: K253489
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: October 23, 2025
Received: October 24, 2025

Dear Kristen Evenson:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253489

Please provide the device trade name(s).

Swoop® Portable MR Imaging® System

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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: Kristen Evenson
Telephone: (612) 251-3030
Email: kevenson@hyperfine.io

Date Prepared: December 5, 2025

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 primary predicate Swoop System (K250236), and the secondary predicate Swoop System (K251276).

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, FLAIR, and DWI sequences.

The subject Swoop System described in this submission includes software modifications related to the pulse sequences.

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	Primary Predicate Swoop Portable MR Imaging System Model 2 (K250236)	Secondary Predicate Swoop Portable MR Imaging System Model 1 (K251276)
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	Same
Patient Population:	Adult and pediatric patients (≥ 0 years)	Same	Same
Anatomical Sites:	Head	Same	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	Same
Energy Used and/or delivered:	Magnetic Resonance	Same	Same
Magnet:			

Specification	Subject Swoop Portable MR Imaging System	Primary Predicate Swoop Portable MR Imaging System Model 2 (K250236)	Secondary Predicate Swoop Portable MR Imaging System Model 1 (K251276)
Field Strength	Model 1 Swoop System 63.3 ± 2.0 mT Model 2 Swoop System 64.9 mT (nominal)	Same as Model 2 of subject device	Same as Model 1 of subject device
Type	Permanent magnet	Same	Same
Patient accessible bore size	Model 1 Swoop System 24.0 in. width, 12.4 in. height Model 2 Swoop System 36.0 in. width, 13.4 in. height	Same as Model 2 of subject device	Same as Model 1 of subject device
Magnet weight	Model 1 Swoop System 705 lbs Model 2 Swoop System 712 lbs	Same as Model 2 of subject device	Same as Model 1 of subject device
Gradient System:			
Maximum gradient amplitude	Model 1 Swoop System X: 24 mT/m, Y: 23 mT/m, Z: 39 mT/m Model 2 Swoop System X: 33.9 mT/m, Y: 33.2 mT/m, Z: 66.2 mT/m	Same as Model 2 of subject device	Same as Model 1 of subject device
Rise Time	Model 1 Swoop System X: 2.1 ms, Y: 2.0 ms, Z: 3.8 ms Model 2 Swoop System X: 1.8 ms, Y: 1.8 ms, Z: 5.1 ms	Same as Model 2 of subject device	Same as Model 1 of subject device
Slew Rate	Model 1 Swoop System X: 24 T/m/s, Y: 22 T/m/s, Z: 21 T/m/s Model 2 Swoop System X: 18.8 T/m/s, Y: 18.4 T/m/s, Z: 13.0 T/m/s	Same as Model 2 of subject device	Same as Model 1 of subject device
RF Coils:			
Coil Type	Transmit/receive	Same	Same
Coil Design	Linear	Same	Same
Other:			
Patient Weight Capacity	1.6kg-200 kg	Same	Same

Specification	Subject Swoop Portable MR Imaging System	Primary Predicate Swoop Portable MR Imaging System Model 2 (K250236)	Secondary Predicate Swoop Portable MR Imaging System Model 1 (K251276)
Operation Temperature	15-30 C	Same	Same
Warm Up Time	<3 minutes	Same	Same
Temperature Control	No	Same	Same
Humidity Control	No	Same	Same
Sequences:			
T1W sequences	• T1 (Standard), T1 (Gray/White) • Advanced Gridding reconstruction	Same	Same
T2W sequences	• T2, T2 (Fast) • Advanced Gridding reconstruction	Same	Same
FLAIR sequences	Model 1 Swoop System • FLAIR • Advanced Gridding reconstruction Model 2 Swoop System • FLAIR, FLAIR (Fast) • Advanced Gridding reconstruction	Same as Model 2 of subject device	Same as Model 1 of subject device
DWI sequences	Model 1 Swoop System • Single Direction DWI/ADC • Multi-direction DWI/ADC • Advanced Gridding + FISTA Model 2 Swoop System • Single Direction DWI/ADC, • Multi-direction DWI/ADC • Advanced Gridding + FISTA	• Single Direction DWI/ADC, Single Direction DWI/ADC (Fast) • Advanced Gridding + FISTA	• Single Direction DWI/ADC • Advanced Gridding + FISTA
Image Post-Processing (All sequences)	• Advanced Denoising • Image orientation transform • Geometric distortion correction • Receive coil intensity correction • Advanced Interpolation • ADC/Trace output (DWI) • DICOM output	• Advanced Denoising • Image orientation transform • Geometric distortion correction • Receive coil intensity correction • Advanced Interpolation • ADC output (DWI) • DICOM output	• Advanced Denoising • Image orientation transform • Geometric distortion correction • Receive coil intensity correction • Advanced Interpolation • ADC output (DWI) • 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. 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 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 62304:2016 • FDA Guidance, "Content of Premarket Submissions for Device Software Functions"
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 standards for named sequences
Cybersecurity	Testing to verify cybersecurity controls and management.	• FDA Guidance, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"
Software Validation	Validation to ensure the subject device meets user needs and performs as intended.	• FDA Guidance, "Content of Premarket Submissions for Device Software Functions"

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

ADVANCED RECONSTRUCTION PERFORMANCE ANALYSIS AND VALIDATION

Performance analysis and validation of the subject device Advanced Reconstruction models was performed for the updated DWI sequence. No images from the test dataset were used for model training. Only the DWI test dataset was updated as no changes were made to T1, T2, or FLAIR sequences, and no changes were made to any of the advanced reconstruction models. Performance analysis and validation of the T1/T2/FLAIR models were leveraged from the predicate device. The test summaries below describe the updated DWI test datasets. The test datasets for the T1, T2, and FLAIR are described in the previous clearances.

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:
The Swoop DWI dataset was updated to include multi-direction DWI images. None of these test images were used in model training. The demographics of the DWI subset are shown below.

<table>
<tr><th>Model / Sequence Group</th><th>#Patients</th><th>#Images</th><th>Demographics</th></tr>
<tr><td>DWI</td><td>8</td><td>31</td><td>Gender:
<table>
<tr><td>Female</td><td>Male</td><td>Unknown</td></tr>
<tr><td>13%</td><td>87%</td><td>0%</td></tr>
</table>
Age:
<table>
<tr><td>0-2</td><td>2-18</td><td>18-35</td><td>35-60</td><td>60+</td><td>Unknown</td></tr>
<tr><td>0%</td><td>0%</td><td>25%</td><td>0%</td><td>75%</td><td>0%</td></tr>
</table>
Ethnicity data not recorded.

Number of sites: 6

Equipment:
<table>
<tr><td>Model 1 Swoop System (V1.9)</td><td>Model 2 Swoop System</td></tr>
<tr><td>13%</td><td>87%</td></tr>
</table>
Included pathology: Post-resection Tumor, ICH, Stroke, TBI, Post-Craniotomy.</td></tr>
</table>

Study Results:
NMSE and SSIM with the included multi-direction DWI dataset were similar to previous 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.

Contrast-to-Noise Ratio Validation

Study Design: Regions of interest (ROI) encompassing pathologies were annotated, and the annotations were reviewed for accuracy by an American Board of Radiology (ABR) certified radiologist. 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:
45 DWI images (41 multi-direction, 4 single-direction) were included for lesion annotation. Inclusion criteria were that the images had at least one visible pathology. The demographics of the DWI dataset are shown below.

<table>
<tr><td>Patients</td><td>12</td></tr>
<tr><td>Images</td><td>45</td></tr>
<tr><td>ROIs</td><td>145</td></tr>
<tr><td>Demographics and other Variability</td><td>Gender:
<table>
<tr><td>Female</td><td>Male</td><td>Unknown</td></tr>
<tr><td>25%</td><td>42%</td><td>33%</td></tr>
</table>
Age:
<table>
<tr><td>0-2</td><td>2-18</td><td>18-35</td><td>35-60</td><td>60+</td><td>Unknown</td></tr>
<tr><td>0%</td><td>0%</td><td>8%</td><td>42%</td><td>33%</td><td>17%</td></tr>
</table>
Ethnicity data not recorded.

Number of sites: 5

Equipment type:
<table>
<tr><td>Model 1 Swoop System (V1.8)</td><td>Model 1 Swoop System (V1.9)</td><td>Model 2 Swoop System</td></tr>
<tr><td>22%</td><td>22%</td><td>56%</td></tr>
</table>
Included pathology: Acute/Subacute Stroke Stroke, Tumor, Post-operative Tumor, Cerebellar metastatic disease, white matter disease, Acute/Subacute Infarct</td></tr>
</table>

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: Four 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:

34 sets of DWI images (30 multi-direction, 4 single-direction) were rated. A set consisted of DWI b=0, DWI (trace-weighted or single direction), and ADC.

<table>
<tr><td>Patients</td><td>34</td></tr>
<tr><td>Images</td><td>102</td></tr>
<tr><td>Demographics and other Variability</td><td>Gender:
<table>
<tr><td>Female</td><td>Male</td><td>Unknown</td></tr>
<tr><td>41%</td><td>35%</td><td>24%</td></tr>
</table>
Age:
<table>
<tr><td>0-2</td><td>2-18</td><td>18-35</td><td>35-60</td><td>60+</td><td>unknown*</td></tr>
<tr><td>0%</td><td>0%</td><td>15%</td><td>26%</td><td>32%</td><td>26%</td></tr>
</table>
*anonymized

Ethnicity data not recorded.

Number of sites: 8

Equipment type:
<table>
<tr><td>Model 1 Swoop System (V1.8)</td><td>Model 1 Swoop System (V1.9)</td><td>Model 2 Swoop System</td></tr>
<tr><td>20%</td><td>10%</td><td>70%</td></tr>
</table>
Included pathology: Acute Stroke, Subacute Stroke, Multiple Sclerosis, White matter disease, Metastatic disease, Post-operative glioma, Tumor, Hydrocephalus, ICH, IVH,</td></tr>
</table>

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 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.