December 16, 2022

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

Re: K223268
Trade/Device Name: BrainInsight™
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: October 21, 2022
Received: October 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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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)*
K223268

Device Name
BrainInsight ™

Indications for Use *(Describe)*
BrainInsight is intended for automatic labeling, spatial measurement, and volumetric quantification of brain structures from a set of low-field MR images and returns annotated and segmented images, color overlays and reports.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

BrainInsight™
510(k) SUMMARY
K223268

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: December 13, 2022

DEVICE IDENTIFICATION

Trade Name: BrainInsight™
Common Name: Automated Radiological Image Processing Software
Regulation Number: 21 CFR 892.2050
Product Code: QIH
Regulatory Class: Class II

PREDICATE DEVICE INFORMATION

The subject BrainInsight is substantially equivalent to the predicate BrainInsight (K220815). The predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION

BrainInsight is a fully automated MR imaging post-processing medical software that provides image alignment, whole brain segmentation, ventricle segmentation, and midline shift measurements of brain structures from a set MR images. The BrainInsight processing architecture includes a proprietary automated internal pipeline based on machine learning tools. The output annotated and segmented images are provided in standard image format using segmented color overlays and reports that can be displayed on third-party workstations and FDA-cleared Picture Archive and Communications Systems (PACS). The high throughput capability makes the software suitable for use in routine patient care as a support tool for clinicians in assessment of low-field (0.064 T) structural MRIs. BrainInsight provides overlays and reports based on 0.064 T 3D MRI series of T1 Gray/White, T2-weighted, T2-Fast, and FLAIR images.

Indications for Use

BrainInsight is intended for automatic labeling, spatial measurement, and volumetric quantification of brain structures from a set of low-field MR images and returns annotated and segmented images, color overlays and reports.

Intended Patient Population

The table below shows the intended patient population.

Application	Patient Population	T1 Gray/White	T2	T2-Fast	FLAIR
Midline Shift	Ages 2+	V	V	V	V
Lateral Ventricles	Ages 2+	V	V	V	V
Whole Brain	Ages 18+	V	V	N/A	N/A

Technological Characteristics

The subject device has the same indications for use, fundamental technology, and operating principles, as the predicate (K220815). Therefore, the subject device is substantially equivalent to the predicate.

Substantial Equivalence Discussion

The table below compares the subject device to the predicate.

Attribute	Subject BrainInsight	Predicate BrainInsight (K220815)
Indications for Use	BrainInsight is intended for automatic labeling, spatial measurement, and volumetric quantification of brain structures from a set of low-field MR images and returns annotated and segmented images, color overlays and reports.	Same
Target Anatomical Sites	Brain	Same
Patient Population	● Adult and pediatric (≥ 2 years) - Lateral ventricles and midline shift applications ● Adult (≥ 18 years) - Whole brain application	Adult (≥ 18 years) - Lateral ventricles, midline shift, and whole brain applications
Technology	● Automated measurement of brain tissue volumes and structures of AI-reconstructed low-field MR images ● Automatic segmentation and quantification of brain structures of AI-reconstructed low-field MR images using machine learning tools	Same
Method of Use	MR images are automatically sent to BrainInsight, and processed images are automatically returned in ~7 minutes	Same
User Interface / Physical Characteristics	● No software required ● Operates in a serverless cloud environment ● User interface through PACS (multiple vendors)	Same
Operating System	Supports Linux	Same

Processing Architecture	Automated internal pipeline that performs: ● segmentation ● volume calculation ● distance measurement ● numerical information display	Same
Data Source	● MRI Scanner: Hyperfine Swoop FSE MRI T1-Gray/White Contrast, T2, T2-Fast and FLAIR scans acquired with specified protocols ● Supports DICOM format as input	● MRI Scanner: Hyperfine Swoop FSE MRI T1 and T2 scans acquired with specified protocols ● Supports DICOM format as input
Output	Provides volumetric measurements of brain structures: ● Includes segmented color overlays and morphometric reports ● Supports DICOM format as output of results that can be displayed on DICOM workstations and PACS	Same
Safety	Automated quality control functions: ● Tissue contrast check ● Scan protocol verification ● Atlas alignment check ● Results must be reviewed by a trained physician ● LV segmentation output quality check	Automated quality control functions: ● Tissue contrast check ● Scan protocol verification ● Atlas alignment check ● Results must be reviewed by a trained physician

PERFORMANCE

As part of demonstrating substantial equivalence to the predicate, a risk analysis was completed to identify the risks associated with the software modifications. Software verification as related to the modifications was performed per IEC 62304:2006 and as recommended in the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The subject device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence.

Each model was trained using a training dataset to optimize parameters and a separate validation dataset to select the best set of parameters. Comparing the training and validation metrics helps to monitor and prevent overfitting. The datasets were augmented to improve robustness using standard techniques that apply transformations to the input data. The testing dataset was separate from training and validation datasets. Each subject was assigned a unique identifier and all subjects in training and validation data were excluded from the test set.

The data collection for the training and validation datasets were done at multiple sites. Each site used the T1-Gray/White contrast and T2, T2-Fast and FLAIR sequences from the FDA cleared Hyperfine Swoop Portable MR imaging system. The datasets were annotated by multiple experts. The entire group of training image sets was divided into segments and each segment was given to a single expert. The expert's determination became the ground truth for each image set in their segment. Each model and application were validated using an appropriate sample size to yield statistically significant results. All test images were acquired using Swoop software versions 8.3 and 8.4. The test set had the following distribution:

Category	Data Distribution
Age	• >2 to 12 years - 20.6% • >12 to <18 years – 8.8% • >18 to 90 years – 70.6%
Gender	• 33% F / 41% M / 25% Anonymized
Pathology	• Stroke (Infarct) • Hydrocephalus • Hemorrhage (SAH, SDH, IVH, IPH) • Mass/Edema • Tumor

Quantitative evaluation was performed to validate performance using software. The performance of the model and the annotators to the consensus-based annotation was computed to ensure that the model performance is no worse than the average annotator. The acceptance criteria were defined based on non-inferiority testing, in which the model discrepancy to the annotators can be no worse than the average annotator discrepancy.

Midline Shift Discrepancy	**T1**	**T2**	**T2-Fast**	**FLAIR**
Model	0.99	0.76	1.00	0.90
Mean Annotator	1.42	1.00	1.38	1.21

Lateral Ventricle Left Discrepancy	**T1**	**T2**	**T2-Fast**	**FLAIR**
Model	0.17	0.20	0.16	0.12
Mean Annotator	0.18	0.24	0.18	0.12

Lateral Ventricle Right Discrepancy	**T1**	**T2**	**T2-Fast**	**FLAIR**
Model	0.19	0.22	0.15	0.13
Mean Annotator	0.19	0.24	0.16	0.13

The mean absolute error was used to calculate the error range for midline shift. Ground truth for midline shift was determined based on the average shift distance of all annotators.

Application	T1 Error	T2 Error	T2-Fast Error	FLAIR Error
Midline Shift	1.01 mm	0.80 mm	0.89 mm	0.75 mm

The mean Dice coefficient was used to calculate the error range for the lateral ventricles and whole brain. Ground truth for segmentation is calculated using Simultaneous Truth and Performance Level Estimation (STAPLE).

Application	Dice Overlap [%]		Volume Differences [%]	
T1	**Device**	**Annotator**	**Device**	**Annotator**
Left Ventricle	85	90	25	9
Right Ventricle	83	90	26	11
Whole Brain	95	97	3	2

Application	Dice Overlap [%]		Volume Differences [%]	
T2	**Device**	**Annotator**	**Device**	**Annotator**
Left Ventricle	84	88	27	21
Right Ventricle	82	87	26	20
Whole Brain	96	97	5	5

Application	Dice Overlap [%]		Volume Differences [%]	
T2-Fast	**Device**	**Annotator**	**Device**	**Annotator**
Left Ventricle	86	91	26	17
Right Ventricle	86	92	23	13

Application	Dice Overlap [%]		Volume Differences [%]	
FLAIR	**Device**	**Annotator**	**Device**	**Annotator**
Left Ventricle	89	93	9	7
Right Ventricle	88	94	11	8

The test results show high accuracy of BrainInsight performance as compared to the reference and annotators and the subject device met all acceptance criteria.

CONCLUSION

Based on the indications for use, technological characteristics, performance results, and comparison to the predicate, the subject BrainInsight has been shown to be substantially equivalent to the predicate and does not present any new issues of safety or effectiveness.