Hyperfine Research, Inc.
% Robert W. Fasciano, Ph.D.
Head of Quality Assurance & Regulatory Affairs
530 Old Whitfield Street
GUILFORD CT 06437

January 7, 2021

Re: K202414
Trade/Device Name: BrainInsight
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 4, 2020
Received: December 7, 2020

Dear Dr. Fasciano:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202414

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.

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K202414

510(k) Summary
(As required by 21 CFR 807.92)

Date Summary Prepared:	August 21, 2020	
Company Name: As required by 807.92(a)(1)	Hyperfine Research, Inc. Robert W. Fasciano, PhD Head of Quality Assurance & Regulatory Affairs 530 Old Whitfield St. Guilford, CT 06437 (617) 435-9098 rfasciano@hyperfine-research.com	
Device Name: As required by 807.92(a)(2)	Device/Trade Name:	BrainInsight
	Device Common Name:	System, Image Processing, Radiological
	Regulation Number:	21 CFR 892.2050
	Regulation Name:	System, Image Processing, Radiological
	Regulation Description:	Picture archive and communications system
	Class:	II
	Product Code:	LLZ
Predicate Device(s): As required by 807.92(a)(3)	NeuroQuant, K170981	
Device Description: As required by 807.92(a)(4)	BrainInsight is a fully automated MR imaging post-processing medical software that image alignment, whole brain segmentation, ventricle segmentation, and midline shift measurements of brain structures from a set of MR images from patients aged 18 or older. The output annotated and segmented images are provided in a 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 (64mT) structural MRIs. BrainInsight provides overlays and reports based on 64mT 3D MRI series of a T1 and T2-weighted sequence. The outputs of the software are DICOM images which include	

volumes that have been annotated with color overlays, with each color representing a particular segmented region, spatial measurement of anatomical structures, and information reports computed from the image data, segmentations, and measurements. The BrainInsight processing architecture includes a proprietary automated internal pipeline that performs whole brain segmentation, ventricle segmentation, and midline shift measurements based on machine learning tools. Additionally, the system's automated safety measures include automated quality control functions, such as tissue contrast check and scan protocol verification. The system is installed on a standard computing platform, e.g. server that may be in the cloud, and is designed to support file transfer for input and output of results.

Statement of Intended Use: As required by 807.92(a)(5)

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.

Comparison of Technological Characteristics with Predicate Devices:
As required by 807.92(a)(6)

Device	**Proposed Device**	**Predicate Device**
	BrainInsight	**NeuroQuant, K170981**
Classification	Class II, LLZ, 21 CFR 892.2050	Class II, LLZ, 21 CFR 892.2050
Intended Use	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.	Automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric data may be compared to reference percentile data
Target Anatomical Sites	Brain	Brain
Technology	▪ Automated measurement of brain tissue volumes and structures ▪ Automatic segmentation and quantification of brain structures using machine learning	• Automated measurement of brain tissue volumes and structures and lesions • Automatic segmentation and quantification of brain structures using a dynamic probabilistic neuroanatomical atlas, with age and gender specificity, based on the MR image intensity
Method of Use	MR images are automatically sent to BrainInsight and processed images are automatically returned in approximately 7 minutes.	User manually sends MR images to NeuroQuant and processed images are automatically returned in approximately 7 minutes.

Comparison of Technological Characteristics with Predicate Devices:
As required by 807.92(a)(6)

Device	**Proposed Device**	**Predicate Device**
	BrainInsight	**NeuroQuant, K170981**
User Interface / Physical Characteristics	• No software required • Operates in a serverless cloud environment • User interface through PACS (multiple vendors)	• Software package installed on User hardware • Operates on off-the-shelf hardware (multiple vendors) • User interface through the software package
Operating System	Supports Linux	Supports Linux, Mac OS X and Windows
Processing Architecture	Automated internal pipeline that performs: - segmentation - volume calculation - distance measurement - numerical information display	Automated internal pipeline that performs: - artifact correction - segmentation - lesion quantification - volume calculation - report generation
Data Source	▪ MRI scanner: Hyperfine FSE MRI scans acquired with specified protocols ▪ Supports DICOM format as input	▪ MRI scanner: 3D T1 MRI scans acquired with specified protocols ▪ NeuroQuant 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 Picture Archive and Communications Systems	Provides volumetric measurements of brain structures and lesions ▪ Includes segmented color overlays and morphometric reports ▪ Automatically compares results to reference percentile data and to prior scans when available ▪ Supports DICOM format as output of results that can be displayed on DICOM workstations and Picture Archive and Communications Systems
Safety	Automated quality control functions ▪ Tissue contrast check ▪ Scan protocol verification ▪ Atlas alignment check ▪ Results must be reviewed by a trained physician	Automated quality control functions ▪ Tissue contrast check ▪ Scan protocol verification ▪ Atlas alignment check ▪ Results must be reviewed by a trained physician

Non-clinical Performance Data: As required by 807.92(b)(1) Performance data was limited to software evaluations to confirm:

- Cybersecurity and PHI protection
- Midline shift
- 3D Coordinates and alignment
- Segmentation

- Data Quality Control
- Audit trail
- User Manual information
- Software control
- Ventricle segmentation
- Midline shift measurement
- Skull stripping

Assessment of Clinical Data: As required by 807.92(b)(2)	No clinical data was required to demonstrate substantial equivalence.
Overall Conclusions: As required by 807.92(b)(3)	Based on the indications for use, technological characteristics, and comparison to predicate device, BrainInsight has been shown to be substantially equivalent to the predicate and is safe and effective for its intended use.