July 12, 2022

Heuron Co., Ltd.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 Thirteenth St. NW
WASHINGTON DC 20004

Re: K203279
Trade/Device Name: Veuron-Brain-mN1
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: Class II
Product Code: LNH, LLZ
Dated: June 10, 2022
Received: June 10, 2022

Dear Dr. Smith:

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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: 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)*
k203279

Device Name
Veuron-Brain-mN1

Indications for Use *(Describe)*
Veuron-Brain-mN1 is intended for use in the post-acquisition image enhancement of 3T MR images of the brain acquired through a 3D gradient-echo sequence. When used in combination with other clinical information, the Veuron-Brain-mN1 application may aid the qualified radiologist with diagnosis by providing enhanced visualization of tissue structures with magnetic susceptibility contrasts in brain 3T MR images.

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."

Heuron
Co., Ltd. 10th Floor, 7, Mirae-ro,
Namdong-gu Incheon, 21558 Republic of
Korea
Tel. +82-32-429-8508 / Fax. +82-32-429-8507

510(k) summary K203279

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter information

Submitter name: Heuron Co., Ltd.
Address: 10th Floor, 7, Mirae-ro, Namdong-gu, Incheon, 21558 Republic of Korea
Phone/Fax: +82-32-429-8508 / +82-32-429-8507
Correspondent Contact: Hogan Lovells US LLP (John J. Smith M.D., J.D., john.smith@hoganlovells.com), +1-202-637-3638, 555 Thirteenth Street, NW, 20004 USA on behalf of Heuron Co., Ltd.
Date of preparation: May 05, 2022

Device information

Proprietary name(s): Veuron-Brain-mN1
Common name: Image Processing Software
Classification name: System, Nuclear Magnetic Resonance Imaging per 21 CFR 892.1000
Product code: LNH, LLZ
Classification panel: Radiology
Device class: II

Device description

Veuron-Brain mN1 is a post-processing software intended to provide visualization, manipulation and reconstruction capabilities, including susceptibility map-weighted images, of 3D gradient multi echo brain 3T MR images. The Veuron-Brain-mN1 aids in the clinical analysis of brain structures from MR images.

- 3D gradient multi echo images are acquired at a specific orientation through the anatomy of interest.

SMWI Algorithm

- Susceptibility map-weighted imaging (SMWI) are reconstructed from the magnitude and Quantitative Susceptibility Mapping (QSM) images of each echo.
- Algorithm output is a 3D SMWI image.
- The software algorithms are not based on machine learning.

Predicate device

SPIN-SWI application software (SpinTech, Inc. K173224, Feb 23, 2018)

Heuron
Co., Ltd. 10th Floor, 7, Mirae-ro,
Namdong-gu Incheon, 21558 Republic of
Korea
Tel. +82-32-429-8508 / Fax. +82-32-429-8507

Indications for Use

Veuron-Brain-mN1 is intended for use in the post-acquisition image enhancement of 3T MR images of the brain acquired through a 3D gradient-echo sequence. When used in combination with other clinical information, the Veuron-Brain-mN1 application may aid the qualified radiologist with diagnosis by providing enhanced visualization of tissue structures with magnetic susceptibility contrasts in brain 3T MR images.

Comparison of indications for use statement

The following table compares indications for use statements between the Veuron-Brain-mN1 and the predicate device (i.e. SPIN-SWI application software). Similar to the predicate device, the Veuron-Brain-mN1 is used for managing patient and case base data, collection, analysis and display of the medical images. The device assists the clinician with the visual evaluation, manipulation, and assessment of pathologies derived from brain scans.

Veuron-Brain-mN1	SPIN-SWI
Subject device (K203279)	Predicate device (K173224)
Veuron-Brain-mN1 is intended for use in the post-acquisition image enhancement of 3T MR images of the brain acquired through a 3D gradient-echo sequence. When used in combination with other clinical information, the Veuron-Brain-mN1 application may aid the qualified radiologist with diagnosis by providing enhanced visualization of tissue structures with magnetic susceptibility contrasts in brain 3T MR images.	The SpinTech, Inc. SPIN- SWI application is intended for use in the post-acquisition image enhancement of MRI acquired 3D gradient-echo images of the brain. When used in combination with other clinical information, the SPIN-SWI application may aid the qualified radiologist with diagnosis by providing enhanced visualization of structures containing venous blood such as cerebral venous vasculature.

Summary of the technological characteristics compared to the predicate device and new device.

The software is similar in uses and application to the predicate device. As stated in the comparison table provided below, both the device and predicates are used to assist the clinician with the visual evaluation, manipulation, and assessment of pathologies derived from brain scans.

Comparison item	Veuorn-Brian-mN1 Subject device (K203279)	SpinTech, Inc. SPIN-SWI application software Predicate device (K173224)
Target user	Qualified radiologist	Qualified radiologist and technologist
Anatomical site	Brain	Brain
Where used	Hospital	Hospital

Heuron
Co., Ltd. 10th Floor, 7, Mirae-ro,
Namdong-gu Incheon, 21558 Republic of
Korea
Tel. +82-32-429-8508 / Fax. +82-32-429-8507

Design features	· Import DICOM data · Perform automatic post-processing · Provide the user confirmation · Export the resulting data only through USB	· Import DICOM data · Perform automatic post-processing · Provide the user confirmation · Export the resulting data through data network
Non-clinical performance	· Bench testing performed to the test functionality of the system.	· Bench testing performed to the test functionality of the system.
Standards	· ISO 14971 · ISO 62304 · IEC 62366	· ISO 14971 · ISO 62304
SW verification and validation	Tested in accordance with verification and validation process and planning. The testing results support that all the system requirements have met their acceptance criteria and are adequate for its intended use.	Tested in accordance with verification processes and planning, The testing results support that all the system requirements have met their acceptance criteria and are adequate for its intended use.
Compatible input data format and modality	· DICOM · MRI (Siemens Healthcare, Philips, 3.0T)	· DICOM · MRI
Input patient data	Manual through keyboard / mouse	Unknown
Output patient data format	DICOM	· Unknown
Study list functionality	Search, Importing and Exporting	Search, Importing and Exporting

Non-clinical study performance

Bench testing is done to show that the system is suitable for its intended use. In order to evaluate the safety of the product, unit tests and integration tests were performed, and all results met the acceptance criteria. The device performance was evaluated using phantom testing representing the range of susceptibility values in the brain tissue. Additionally, the device performance was also evaluated on clinical images using CNR/SNR metrics. The scanner models used for the testing were Siemens Healthcare's and Philips's and field strength was 3T. The predefined acceptance criteria were met to demonstrate substantial equivalence to the predicate.

Conclusion

By virtue of its intended use, design features, and technological characteristics, Veuron-Brain-mN1 is substantially equivalent to a device that has been approved for marketing in the United States. The non-clinical performance data shows that Veuron-Brain-mN1 is as safe and effective as the predicate device without raising any new safety and/or effectiveness concerns.