October 13, 2023

Heuron Co., Ltd.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
Columbia Square 555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K231642
Trade/Device Name: Veuron-Brain-pAb3
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 13, 2023
Received: September 13, 2023

Dear John 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 (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.

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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

K231642

Device Name
Veuron-Brain-pAb3

Indications for Use *(Describe)*

Veuron-Brain-pAb3 is software for the registration, fusion, display, and analysis of medical images from multiple modalities including MRI and PET. The software aids clinicians in the assessment and quantification of pathologies from PET Amyloid scans of the human brain. It enables anatomic analysis and visualization of amyloid protein concentration through the calculation of standard uptake volume ratio (SUVR) within target regions of interest and comparison to those within the reference regions. The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with radio-tracer and disease combinations.

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.

510(k) SUMMARY
Heuron Co., Ltd.'s Veuron-Brain-pAb3

Submitter Information
Company Name: Heuron Co., Ltd.
Address:10F, C, 150, Yeongdeungpo-ro, Yeongdeungpo-gu, Seoul, 07292, Republic of Korea

Contact Person: John J. Smith, M.D., J.D.
Phone: +1 202 637 3638
Facsimile: +1 202 637 5910
Date Prepared: September 5, 2023

Name of Device: Veuron-Brain-pAb3
Common or Usual Name: Medical Imaging Software
Classification Name: System, Image Processing, Radiological
Regulatory Class: 21 CFR 892.2050
Product Code: LLZ

Predicate Device
Manufacturer name: Heuron Co., Ltd.
Device's trade name: Veuron-Brain-pAb2
510(K) number: K213801
Regulatory Class: 21 CFR 892.2050
Product Code: LLZ

Device Description
The Veuron-Brain-pAb3 is a standalone software for quantitative analysis of the PET amyloid by automatically calculating the "Standardized Uptake Value Ratio (SUVR)". The calculated result is only used as a reference to support the accuracy of the medical professional's diagnosis of dementia in patients. It also helps with accurate visual interpretation through visualization functions. Various PET amyloid images can be processed by using diverse options provided for users to choose in the image process.

Intended Use / Indications for Use
The Veuron-Brain-pAb3 is a software for the registration, fusion, display and analysis of medical images from multiple modalities including MRI and PET. The software aids clinicians in the assessment and quantification of pathologies from PET amyloid scans of the human brain. It enables automatic analysis and visualization of amyloid concentration through the calculation of standard uptake value ratio (SUVR) within target regions of interest and comparison to those within the reference regions. The software is deployed via medical imaging workplace and is organized as a series of workflows which are specific to use with radio tracer and disease combinations.

Summary of Technological Characteristics
Image load and SUVR calculation is the technological principle for both the subject and predicate devices. Both devices load the MR and PET images, and calculate SUVR for the brain. At a high level, the subject and predicate devices are based on the following same technological elements:

- Image load
- Overlay
- SUVR calculation
- Report

The following technological differences exist between the subject and predicate devices:

- Addition of a worklist. Veuron-Brain-pAb3 includes a worklist showing the user of the list of patients.
- Addition of a tracer option. With Veuron-Brain-pAb3, users can select the tracer for beta amyloid. By providing an option (reference region) for tracer, helps users identify appropriate brain regions for analysis.

A table comparing the key features of the subject and predicate devices is provided below.

	Subject device	**Predicate device (K213801)**
Device name	Veuron-Brain-pAb3	Veuron-Brain-pAb2
Manufacturer	Heuron Co., Ltd.	Heuron Co., Ltd.
Product code	LLZ	LLZ
Indications for use	The Veuron-Brain-pAb3 is software for the registration, fusion, display, and analysis of medical images from multiple modalities including MRI and PET. The software aids clinicians in the assessment and quantification of pathologies from PET Amyloid scans of the human brain. It enables anatomic analysis and visualization of amyloid protein concentration through the calculation of standard uptake volume ratio (SUVR) within target regions of interest and comparison to those within the reference regions. The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with radio-tracer and disease combinations.	The Veuron-Brain-pAb2 is software for the registration, fusion, display, and analysis of medical images from multiple modalities including MRI and PET. The software aids clinicians in the assessment and quantification of pathologies from PET Amyloid scans of the human brain. It enables automatic analysis and visualization of amyloid protein concentration through the calculation of standard uptake volume ratio (SUVR) within target regions of interest and comparison to those within the reference regions. The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with radiotracer and disease combinations.
Target anatomical site	Brain	Brain
Where used	Hospital	Hospital
Design features	Import DICOM data Perform automatic post-processing Provide the user confirmation Export the resulting data through a network or USB	Import DICOM data. Perform automatic post-processing. Provide the user confirmation Export the resulting data through a network or USB
Physical characteristics	Software package	Software package

	Subject device	Predicate device (K213801)
	Operates on off-the-shelf hardware (multiple vendors)	Operates on off-the-shelf hardware (multiple vendors)
Operating system	Server: Linux (Ubuntu 18.04 LTS or higher) Client: Windows 10 or higher	Server: Ubuntu 16.04 LTS or higher Client: Windows 10, 64-bit
Standards	ISO 14971 IEC 62304 IEC 62366	ISO 14971 IEC 62304 IEC 62366
Software 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 and validation 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 & NIfTI PET, MRI	DICOM & NIfTI PET, MRI
Input patient data	Manual through keyboard/mouse	Manual through keyboard/mouse
Output patient data	Picture: PNG Report: PNG, csv	Picture: PNG Report: csv
Study list functionality	Search Importing Exporting	Search Importing Exporting
Worklist	Yes	No
Tracer option	Yes, can select the tracer for beta amyloid Tracer list ・ 18F-Flutemetamol (FMM) ・ 18F-Florbetapir (FBP) ・ 18F-Florbetaben (FBB)	No, cannot select the tracer for beta amyloid
Segmentation Algorithm	・ Calculate the volume by using a Convolutional Neural Network (CNN) model. ・ CNN model has trained 3D brain MR images were collected from one domestic institution	・ Calculate the volume by using a Convolutional Neural Network (CNN) model. ・ CNN model has trained 3D brain MR images were collected from one domestic institution.

Non-Clinical Performance Testing

Software verification and validation was performed to demonstrate the new functions perform as intended. No clinical testing was conducted.

Conclusions

The Veuron-Brain-pAb3 is as safe and effective as the Veuron-Brain-pAb2. The Veuron-Brain-pAb3 has the same intended uses and indications, it has similar technological characteristics, and principles of operation as its predicate device. In addition, the minor technological differences between the Veuron-Brain-pAb3 and its predicate devices raise no new issues of safety or effectiveness.