Heuron Co., Ltd.
% Edward Park
CEO
LightenBridge LLC
4408 Tortuga Ln
McKinney, TX 75070

February 4, 2022

Re: K213801
Trade/Device Name: Veuron-Brain-pAb2
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 6, 2021
Received: December 6, 2021

Dear Edward Park:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213801

Device Name
Veuron-Brain-pAb2

Indications for Use *(Describe)*
The Veuron-Brain-pAb2 is a software for the registration, fusion, display and analysis of medical images from multiple modalities including MRI and PET. The software aids clinician 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 ratios (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.

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.

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510(k) Summary

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	Tel. 82-32-429-8508 / Fax. 82-32-429-8507
Contact Person:	Edward Park, official correspondent of Heuron Co., Ltd.
Date of submission:	Sep 01, 2020

Device Information

Proprietary Name(s):	Veuron-Brain-pAb2
Common Name:	Image Processing Software
Classification Name:	Medical Image Management and Processing System per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	II

Device Description

The Veuron-Brain-pAb2 is stand-alone software to automatically calculate the "Standardized Uptake Value Ratio (SUVR)" for quantitative analysis of amyloid PET. The calculated result is just used as a reference supporting the accuracy of the diagnosis of patients' dementia for the medical professional. It also helps with accurate visual interpretation through visualization functions. Various amyloid PET images can be processed by providing a variety of options for users to choose in the image process.

Predicate Device

- Veuron-Brain-pAb (Heuron Co., Ltd. K203142, 01/15/2021)

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Intended Use

Veuron-Brain-pAb2 is software for brain image analysis. Veuron-Brain-pAb2 is stand-alone software that provides the medical professional with the means to process and display medical images from modalities such as MR and PET. Additionally it calculates deposition of β amyloid protein in the cerebral cortex. The calculate feature improve the accuracy necessary for the medical professional. It provides automated quantitative and statistical analysis by automatically registering PET/MRI brain scans to a standard template and comparing intensity values to a reference database or to other PET/MRI scans on a voxel by vaxel basis, within stereotactic surface projections, or within standardized regions of interest.

Comparison of Indications for Use Statements

The following table compares Indications for Use Statements between the Veuron-Brain-pAb2 and the predicate device, Veuron-Brain-pAb. identical to the predicate device, the Veuron-Brain-pAb2 is used for managing patient and case base data, collection, analysis, fusion, and display of the medical images. The device assists the clinician with the visual evaluation, assessment and quantification of pathologies derived from brain sans.

Veuron-Brain-pAb2	Veuron-Brain-pAb
Proposed device	Proposed device
The Veuron-Brain-pAb2 is a software for the registration, fusion, display and analysis of medical images from multiple modalities including MRI and PET. The software aids clinician 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 ratios (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.	The Veuron-Brain-pAb is a software for the registration, fusion, display and analysis of medical images from multiple modalities including MRI and PET. The software aids clinician 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 ratios (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.

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

The software is similar in uses and applications to the predicate device. As stated in the comparison table provided below, both the proposed and the predicate devices are used to assist the Clinician with the visual evaluation, assessment and quantification of pathologies derived from brain scans.

Comparison Item	Veuron-Brain-pAb2	Veuron-Brain-pAb
Target Users	Trained Medical professionals	Trained Medical professionals
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 data network or USB	Import DICOM data Perform automatic post-processing Provide the user confirmation Export the resulting data only through USB
OS	Server: Ubuntu 16.04 LTS or higher Client: Windows 10, 64-bit	Windows 10, 64-bit
Non-clinical Performance	Bench testing performed to test the functionality of the system and measurement tools.	Bench testing performed to test the functionality of the system and measurement tools.
Standards	· ISO 14971 · IEC 62304 · IEC 62366	· ISO 14971 · IEC 62304 · IEC 62366
SW verification and validation	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.	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 Format	Pictures: PNG Report: .csv	Pictures: PNG Report: .csv

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Comparison Item	Veuron-Brain-pAb2	Veuron-Brain-pAb
Study list functionality	Search, Importing, Exporting	Search, Importing, Exporting

Non-Clinical Study performance

Bench testing is done to show that the system is suitable for its intended use and that the measurement tool performance meets its pre-defined requirements. This did not reveal any issues with the system, demonstrating that the performance of Veuron-Brain-pAb2 is as safe and effective as its predicate device.

Conclusion

By virtue of its intended use, design features, and technological characteristics, Veuron-Brain-pAb2 is substantially equivalent to the predicate device. The non-clinical performance data shows that Veuron-Brain-pAb2 is as safe and effective as the predicate device without raising any new safety and/or effectiveness concerns.