Heuron Co., Ltd.
% Mr. Edward Park
CEO
LightenBridge LLC
4408 Tortuga Lane
MCKINNEY TX 75070

January 15, 2021

Re: K203142
Trade/Device Name: Veuron-Brain-pAb
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: October 20, 2020
Received: October 20, 2020

Dear Mr. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K2O3142

Device Name
Veuron-Brain-pAb

Indications for Use *(Describe)*

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.

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
K203142

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-pAb
Common Name:	Image Processing Software
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050
Product Code:	LLZ
Classification Panel:	Radiology
Device Class:	II

Device Description

The Veuron-Brain-pAb is stand-alone software to automatically calculate the "Standardized Uptake Value Ratio (SUVR)" for quantitative analysis of amyloid PET. The calculated result supports 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

< Primary predicate device >

- Scenium 2.0 (Siemens Medical Solutions USA, Inc. K121074, 06/08/2012)

< Secondary device >

- MIM 4.0 (NEURO) (MlMvista Corp. K060816, 05/16/2006)

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Intended Use

The Veuron-Brain-pAb is a display and analysis software to aid the Clinician in the assessment and quantification of pathologies taken from amyloid PET scans. The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with particular drug and disease combinations. The software aids in the assessment of human brain scans enabling automated analysis through quantitative analysis of amyloid PET. It facilitates comparison with those different regions and calculation of standard uptake value ratios between regions of interest on the medical image.

Comparison of Indications for Use Statements

The following table compares Indications for Use Statements between the Veuron-Brain-pAb and the two predicate devices, i.e. Scenium 2.0 and MIM 4.0 (NEURO). Similar to the other predicate devices, the Veuron-Brain-pAb 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-pAb	Simens Scenium 2.0	MlMvista Corp. MIM 4.0 (NEURO)
Proposed device	Primary predicate device (K121074)	Secondary predicate device (K060816)
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	The Scenium display and analysis software has been developed to aid the Clinician in the assessment and quantification of pathologies taken from PET and SPECT scans. The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with particular drug and disease combinations. The software aids in the assessment of human brain scans enabling automated analysis through quantification of mean pixel values located within standard regions of interest. It facilitates comparison with	MIM 4.0 (NEURO) is a software package that provides the physician with the means to display, register and fuse medical images from multiple modalities. Additionally, it evaluates cardiac left ventricular function and perfusion including left ventricular end-diastolic volume, end-systolic volume, and ejection fraction. The Region of Interest (ROI) feature reduces the time necessary for the physician to define objects in medical image volumes by providing an initial definition of object contours. The objects include

Veuron-Brain-pAb	Simens Scenium 2.0	MlMvista Corp. MIM 4.0 (NEURO)
Proposed device	Primary predicate device (K121074)	Secondary predicate device (K060816)
medical imaging workplaces and is organized as a series of workflows which are specific to use with radio-tracer and disease combinations.	existing scans derived from FDG-PET, amyloid-PET, and SPECT studies and calculation of uptake ratios between regions of interest.	but are not limited to tumors and organs. MIM 4.0 (NEURO) also aids the physician in the assessment of PET/SPECT brain scans. It provides automated quantitative and statistical analysis by automatically registering PET/SPECT brain scans to a standard template and comparing intensity values to a reference database or to other PET/SPECT scans on a voxel by voxel basis, within stereotactic surface projections, or within standardized regions of interest.

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

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

Comparison Item	Veuron-Brain-pAb	Simens Scenium 2.0 (Primary predicate)	MlMvista Corp. MIM4.0 (NEURO) (2nd predicate)
Target Users	Trained Medical professionals	Trained Medical professionals	Trained Medical professionals
Anatomical Site	Brain	Brain	Brain
Where Used	Hospital	Hospital	Hospital
Design Features	Import DICOM data Perform automatic post-processing	Import DICOM data Perform automatic post-processing	Import DICOM data Perform automatic post-processing

Comparison Item	Veuron-Brain-pAb	Simens Scenium 2.0 (Primary predicate)	MlMvista Corp. MIM4.0 (NEURO) (2nd predicate)
	Provide the user confirmation Export the resulting data only through USB	Provide the user confirmation Export the resulting data through data network	Provide the user confirmation Export the resulting data only through data network
OS	Windows 10, 64-bit	Windows 7, 64-bit	Windows 2000/XP
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.	Bench testing performed to test the functionality of the system and measurement tools.
Standards	· ISO 14971 · IEC 62304 · IEC 62366	· ISO 14971 · IEC 62304	· ISO 14971 · IEC 62304
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.	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 PET, SPECT, MRI, CT	DICOM PET, SPECT, MRI, CT
Input Patient Data	Manual through keyboard/mouse	Manual through keyboard/mouse	Manual through keyboard/mouse
Output Patient Data Format	Pictures: PNG Report: .csv	Pictures: JPEG Report: DICOM	
Study list functionality	Search, Importing, Exporting	Search, Importing, Exporting, Deleting	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-pAb is as safe and effective as its predicate devices.

Conclusion

By virtue of its intended use, design features, and technological characteristics, Veuron-Brain-pAb 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-pAb is as safe and effective as the predicate devices without raising any new safety and/or effectiveness concerns.