August 5, 2022

NEUROPHET, Inc.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave., STE 160
IRVINE CA 92612

Re: K221405
Trade/Device Name: Neurophet SCALE PET
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 4, 2022
Received: May 16, 2022

Dear Priscilla Chung:

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 and Part 809); 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
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)*

K221405

Device Name
Neurophet SCALE PET

Indications for Use *(Describe)*

Neurophet SCALE PET 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/FDG 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

(K221405)

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. **Date:** 7/20/2022

2. **Applicant / Submitter**

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3. **U.S. Designated Agent**

Priscilla Chung
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4. **Trade/Proprietary Name:**

Neurophet SCALE PET

5. **Common Name:**

Medical Image Processing Software

6. **Classification:**

Medical Image Management and Processing System (21CFR 892.2050, Product code LLZ, Class 2, Radiology)

7. **Device Description:**

Neurophet SCALE PET is a standalone software product that automatically calculates standardized uptake value ratios (SUVR) and provides quantified calculation results for quantitative analysis of FDG and Amyloid PET images. The calculation results are intended to aid clinicians in diagnosing patients' pathologies. Furthermore, the function provided to

visualize the results of the analysis of the image is designed to help clinicians perform accurate visual interpretation.

Functions and workflow supported by the product are as follows:
The user may set specified region as reference region, however, in order to achieve reliable constant count in the reference region, FDA recommends the selection of the pons or cerebellar white matter as reference region for assessment of SUVR in FDG PET imaging.

Because this product complies with the standard DICOM medical imaging protocol, it can be used by being linked with picture archive and communications systems (PACS).

8. Indication for use:

Neurophet SCALE PET 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/FDG 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.

9. Predicate Device:

- Primary Predicate:
  Veuron-Brain-pAb (K203142) by HEURON CO., LTD.

- Reference Device:
  Scenium 2.0 (K121074) by Siemens Medical Solutions USA, Inc

10. Substantial Equivalence:

	Subject Device	Primary predicate Device	Reference Device
Device name	Neurophet SCALE PET	Veuron-Brain-pAb	Scenium 2.0
510(k)	k221405	k203142	k121074
Manufacturer	NEUROPHET, Inc.	HEURON CO., LTD.	Siemens Medical Solutions USA, Inc
Product Code	LLZ	LLZ	LLZ
Indications for Use	Neurophet SCALE PET 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/FDG 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.	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.	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 deploted 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 existing scans derived from FDG-PET, amyloid PET, and SPECT studies and calculation of uptake ratios between regions of interest.
Target Anatomical Sites	Brain	Brain	Brain
Where Used	Hospital	Hospital	Hospital
Design Features	• Import DICOM data Perform automatic post-processing • Provide the user confirmation • Export the resulting data through data network or Local PC	• 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 only through data network

Physical characteristics	• Software package • Operates on off-the-shelf hardware (multiple vendors)	• Software package • Operates on off-the-shelf hardware (multiple vendors)	No software required • Operates in a serverless cloud environment • User interface through PACS (multiple vendors)
Operating System	Windows 10, 64-bit	Windows 10, 64-bit	Windows 7, 64-bit
Standards	• ISO 14971 • IEC 62304 • IEC 62366	• ISO 14971 • IEC 62304 • IEC 62366	• ISO 14971 • IEC 62304 • IEC 62366
Software 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 & NiFTI PET, MRI	DICOM PET, SPECT, MRI, CT
Input Patient Data	Manual through keyboard/mouse	Manual through keyboard/mouse	Manual through keyboard/mouse
Output Patient Data	Pictures: nii.gz Report: .csv, pdf	Pictures: PNG Report: .csv	Pictures: JPEG Report: DICOM
Study list functionality	Search, Importing, Exporting	Search, Importing, Exporting	Search, Importing, Exporting, Deleting

The subject device (Neurophet SCALE PET) and the predicate device are the image analysis software for PET images scanned the Human Brain.

- Both devices have the same intended purpose to support clinicians in the assessment and quantification of pathology through PET scan images.
- Both devices automatically calculate the Standardized Uptake Value Ratio (SUVR) value using brain MRI and PET images and provide quantitative analysis results as a report.
- Both devices are DICOM compatible and operate on off-the-shelf hardware. Both devices are used by physicians skilled in brain MR imaging.
- The compatible input data format and modality are also the same.

Therefore, Neurophet SCALE PET is functionally similar and improved from a previous 510(k) market-cleared Veuron-Brain-pAb software device (K203142).

Following are the differences between Neurophet SCALE PET and the predicate device:

Item	Neurophet SCALE PET	Veuron-Brain-pAb	Scenium 2.0
Supported PET image types	Amyloid PET FDG PET	Amyloid PET	Amyloid PET FDG PET SPECT
Output	Pictures: nii.gz	Pictures: PNG	Pictures: JPEG

Patient Data	Report: .csv, pdf	Report: .csv	Report: DICOM
Design Features	Export the resulting data network or user PC	Export the resulting data only through USB	Export the resulting data only through data network

Although both are technically similar, there is a difference in the supported PET image type. The subject device supports Amyloid PET and FDG PET analysis, while the predicate device, Veuron-Brain-pAb(K203142), supports only Amyloid PET analysis. So, we additionally identified a reference device that covered the scope of supported PET image type for the subject device. The reference device, Scenium 2.0(K121074), is an image analysis software that has a similar purpose to the subject device and can support Amyloid PET, FDG PET, SPECT image analysis.

Also, there is a difference in output patient data between the subject device and the predicate device. However, this is only a difference in file format, and the types of output data that users can obtain are the same.

In the data export path, the predicate device can export the data only through a USB. So, we additionally identified a reference device that can export resulting data through data network. Therefore, it is possible to cover this difference by considering both the predicate device and the reference device.

11. Performance Data:

SW verification/validation and the measurement accuracy test were conducted to establish the performance, functionality and reliability characteristics of the subject devices. The device passed all of the tests based on pre-determined Pass/Fail criteria.

The result of the performance test is as follows.

1) Segmentation Accuracy
The performance of the Segmentation function was evaluated by comparing the Dice similarity coefficient (DSC) between Neurophet SCALE PET-produced segmentation and manual segmentation done by experts. For the DSC evaluation, the subject device performed a DSC of 86.39±3.12% on major subcortical brain structures.

2) SUVR Calculation Reliability
The reliability of the SUVR results was evaluated by statistical test using intraclass correlation coefficient between Neurophet SCALE PET-and conventional PET processing tools. For the ICC, the subject device was shown the good reliability (all ROI ICC scores > 0.6).

12. Conclusion:

The subject device is substantially equivalent in the areas of technical characteristics, general

function, application, and indications for use. The new device does not introduce a fundamentally new scientific technology, and the device has been validated through system level test. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.