May 15, 2026

Neurophet., Inc.
Jin Woo Jeong
RA Team member
12f, 124, Teheran-Ro, Gangnam-Gu
Seoul, Republic Of Korea

Re: K252563
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: QIH, LLZ
Dated: March 20, 2026
Received: March 20, 2026

Dear Jin Woo Jeong:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252563

Device Name

Neurophet SCALE PET

Indications for Use *(Describe)*

Neurophet SCALE PET is 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 scans of the human brain. It enables automatic analysis and visualization of brain PET through the calculation of standard uptake volume ratios (SUVR) and its derived quantitative values 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

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(1)]

05/13/2026

2. Submitter's Information [21 CFR 807.92(a)(1)]

Name of Manufacturer	NEUROPHET, Inc.
Address	12F, 124, Teheran-ro, Gangnam-gu, Seoul 06234, Republic of Korea.
Contact Name	Jin Woo Jeong
Telephone No.	82-10-3614-9923
Email Address	jwjeong@neurophet.com

3. Identification of Proposed Device(s) [21 CFR 807.92(a)(2)]

510(k) Number	K252563
Trade/Device/Model Name	Neurophet SCALE PET
Device Classification Name	Medical image management and processing system
Regulation Number	21 CFR 892.2050
Classification Product Code	QIH, LLZ
Device Class	Class II
510(k) Review Panel	Radiology

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

- **Predicate device #1**

510(k) Number	K221405
Trade/Device/Model Name	SCALE PET
Device Classification Name	Medical image management and processing system
Regulation Number	892.2050
Classification Product Code	LLZ
Device Class	Class II
510(k) Review Panel	Radiology

- **Predicate device #2**

510(k) Number	K252496
Trade/Device/Model Name	Neurophet AQUA AD Plus
Device Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Classification Product Code	QIH, LLZ
Device Class	Class II
510(k) Review Panel	Radiology

These predicate devices have not been subject to a design-related recall.

5. Description of the Device [21 CFR 807.92(a)(4)]

Neurophet SCALE PET is designed for aiding physicians to make a medical decision for neurodegeneration and cognitive impairment. The system streamlines clinical workflow from patient registration to analysis result archive and report generation with software-based features.

6. Indications for Use [21 CFR 807.92(a)(5)]

Neurophet SCALE PET is 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 scans of the human brain. It enables automatic analysis and visualization of brain PET through the calculation of standard uptake volume ratios (SUVR) and its derived quantitative values 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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7. Technological Comparison [21 CFR 807.92(a)(6)]

Provided below is a table that compares technological characteristics of the Neurophet SCALE PET and the predicate device

[Table 1. Comparison of Proposed Device to Predicate Devices]

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
K Number	K252563	K221405	K252496	-
Manufacturer	NEUROPHET, Inc.	NEUROPHET, Inc.	NEUROPHET, Inc.	-
Product Name	Neurophet SCALE PET (V2.0)	Neurophet SCALE PET	Neurophet AQUA AD Plus (v3.0)	-
Product Code	QIH, LLZ	LLZ	QIH, LLZ	Identical.
Regulation Number	892.2050	892.2050	892.2050	Identical
510(k) Review Panel	Radiology	Radiology	Radiology	Identical
Indications for Use	Neurophet SCALE PET is 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 scans of the human brain. It enables automatic analysis and visualization of brain PET through the calculation of standard uptake volume ratios (SUVR) and its derived quantitative values within target regions of interest and comparison to those within the reference	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	Neurophet AQUA AD Plus is intended for automatic labeling, visualization, and volumetric quantification of segmentable brain structures and lesions, as well as SUVR quantification from a set of MR and PET images. Volumetric measurements may be compared to reference percentile data.	Identical

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
	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.	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.		
Design and Incorporated Technology	• Automatic segmentation and quantification of brain structures based on MR and PET image intensities using static deep learning technologies. • Quantifies the standardized uptake value of the region of interest and then calculates the ratio of the standardized uptake value(SUVR) by comparing it with the standardized uptake value of a referenced region. • Automatic calculation of the Centiloid scale by SUVR, which indicate the degree of amyloid accumulation, to quantify the severity of dementia.	• Automatic segmentation and quantification of brain structures based on the MR image intensity and static deep-learning technologies • Quantifies the standardized uptake value of the region of interest and then calculates the ratio of the standardized uptake value (SUVR) by comparing it with the standardized uptake value of a referenced region.	• Automated measurement of brain tissue volumes and structures and lesions • Automatic segmentation and quantification of brain structures and lesions based on MR and PET image intensities using static deep learning technologies. • Quantifies the standardized uptake value of the region of interest and then calculates the ratio of the standardized uptake value(SUVR) by comparing it with the standardized uptake value of a referenced region. • Automatic calculation of the Centiloid scale by SUVR, which	Similar

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
			indicate the degree of amyloid accumulation, to quantify the severity of dementia.	
Physical characteristics	• Software package • Operates on off-the-shelf hardware (multiple vendors)	• Software package • Operates on off-the-shelf hardware (multiple vendors)	• Software package Operates on off-the-shelf hardware (multiple vendors)	Identical
Operating System	Supports windows	Supports windows	Supports windows	Identical
Processing Architecture	Automated internal pipeline that performs: -artifact correction -segmentation -SUVR calculation -Centiloid Scale calculation -report generation	Automated internal pipeline that performs: -artifact correction -segmentation -SUVR calculation -report generation	Automated internal pipeline that performs: -artifact correction -segmentation -lesion quantification -volume calculation -SUVR calculation -Centiloid Scale calculation -report generation	Similar
Data Source	• MRI scanner: 3D T1-weighted • PET scanner: Amyloid PET, FDG PET • SCALE PET Supports DICOM format as input	• MRI scanner: 3D T1-Weighted • PET scanner: Amyloid PET, FDG PET • SCALE PET Supports DICOM format as input	• MRI scanner: 3D T1 and T2 FLAIR, T2* GRE / SWI MRI • PET scanner: Amyloid PET AQUA AD Plus Supports DICOM format as input	Identical
Output	• provides the capabilities to adjust image transparency and apply color mapping to	• provides the capabilities to adjust image transparency and apply color mapping to	• Provides volumetric measurements of brain structures and lesions	Similar

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
	individual brain structures • Quantifies the standardized uptake value (SUV) of the region of interest and calculates the standardized uptake value ratio (SUVR) by comparing it with the SUV of a reference region. The calculated SUVR is then converted into a Centiloid unit and provided. • Supports DICOM format as output of results that can be displayed on DICOM workstations and Picture Archive and Communications Systems	individual brain structures • Quantifies the standardized uptake value (SUV) of the region of interest and calculates the standardized uptake value ratio (SUVR) by comparing it with that of a reference region. • Supports DICOM format as output of results that can be displayed on DICOM workstations and Picture Archive and Communications Systems	• provides the capabilities to adjust image transparency and apply color mapping to individual brain structures • Automatically compares results to reference percentile data and to prior scans when available • Quantifies the standardized uptake value (SUV) of the region of interest and calculates the standardized uptake value ratio (SUVR) by comparing it with the SUV of a reference region. The calculated SUVR is then converted into a Centiloid unit and provided.Supports DICOM format as output of results that can be displayed on DICOM workstations and Picture Archive and Communications Systems	
Safety	Automated quality control functions: -Tissue contrast check	Automated quality control functions: -Tissue contrast check	Automated quality control functions: -Tissue contrast check	Identical

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
	-Scan protocol verification -Atlas alignment check Results must be reviewed by a trained physician	-Scan protocol verification -Atlas alignment check Results must be reviewed by a trained physician	-Scan protocol verification -Atlas alignment check Results must be reviewed by a trained physician	

The technological parameters of the Neurophet SCALE PET are either identical or similar to those of the predicate devices, and the differences do not raise new types of questions regarding the safety and effectiveness for the proposed indications for use.

8. Non-Clinical Test Summary

The following data were provided in support of the substantial equivalence determination:

1) Software Validation

The Neurophet SCALE PET contains enhanced document level of concern software. The software was designed and developed according to a software development process and was verified and validated. Software information is provided in accordance with FDA guidance:

- "Content of Premarket Submissions for Device Software Functions," dated June 14, 2023.

2) Performance characteristics

Neurophet SCALE PET was validated for its intended use and evaluated to determine substantial equivalence to the predicate devices. The device consists of AI modules for automated segmentation and quantitative analysis using MR and PET images. Performance characteristics were established through a series of independent tests, summarized as follows:

a) Training Data

Distinct training datasets were constructed for core module (T1-SegEngine), using clinically normal subjects, comprising a combination of public research datasets (ADNI, HCP, IXI, AIBL, and PPMI), and private hospital datasets collected from the Republic of Korea (Catholic university, Yeouido ST. Mary's hospital). Training data covered:

- Adult subjects across a broad age range (approximately 20–80+ years), with both sexes represented and including multiple racial/ethnic groups (e.g., White, Asian, Black).
- MRI acquired on major vendor platforms (GE, Siemens, Philips) at 3T using standard 3D T1-weighted.

Training and test datasets were strictly separated at the subject level. No images or manual labels from the training datasets were reused in the test datasets, ensuring independence of performance estimates.

b) Performance Test

Standalone performance tests were conducted for all modules using datasets that were completely independent from those used for development and training. These test sets reflected a variety of scanner vendors, image acquisition protocols, geographic regions, demographic backgrounds, and clinical diagnoses.

T1-SegEngine: The T1-SegEngine module was validated using datasets collected from multiple acquisition sites. The dataset included both male and female subjects, with age groups ranging from 20 to 80+, and racial and ethnic groups including White, Asian, Black, and Hispanic/Latino. Clinical subgroups and potential confounders including scanner vendor, magnetic field strength, and diagnosis (clinically normal, mild cognitive impairment, and Alzheimer's disease) were evaluated through subgroup analysis. MR images were acquired across multiple sites using scanners from GE, Siemens, and Philips with both 1.5T and 3.0T field strengths.

Segmentation accuracy was assessed using Dice Similarity Coefficient (DSC) on an independent test dataset of 64 subjects (one MR image per subject) for both cortical and subcortical brain structures. The reference standard was established through manual segmentation performed by four trained experts. All regions met the predefined acceptance criteria (major cortical: mean DSC 0.80±0.03, 95% confidence interval [0.79, 0.81], acceptance range in [0.75, 0.85]; major subcortical: mean DSC 0.85±0.03, 95% confidence interval [0.84, 0.86], acceptance range in [0.80, 0.90]). Subgroup analyses stratified by sex, age, race, scanner vendor, magnetic field strength, and diagnosis demonstrated that the acceptance criteria were satisfied across all subgroups for both cortical and subcortical structures.

Reproducibility of T1-SegEngine segmentation was evaluated in 50 MR image pairs collected from the same subjects scanned within a 6- to 12-month interval, using Average Volume Difference Percentage (AVDP). All cortical and subcortical structures met the predefined acceptable range of [1.0%, 5.0%] (cortical: 1.95±0.88, 95% confidence interval [1.70, 2.20]; subcortical: 1.87±0.80, 95% confidence interval [1.65, 2.10]), and the acceptance criteria were satisfied across all subgroups.

PET-Engine: Quantitative SUVR values were validated against an FDA-cleared predicate (K221405) in 74 paired MRI–PET datasets per tracer (74 Amyloid PET and 74 FDG PET) and across acquisition sites. Excellent consistency was achieved in all regions reported to the user (all ICC values using FDG PET $\geq$ 0.937 and using Amyloid PET $\geq$ 0.990; acceptance criterion: $\geq$ 0.6).

Furthermore, supporting analysis in the worst-case ROIs demonstrated that all paired SUVR differences fell within the predefined range of ±0.10 for both amyloid PET (100%, 74/74) and FDG PET (100%, 74/74), confirming that the consistency criterion was met even in the most challenging ROIs.

Repeatability/Reproducibility for SUVR were validated in 49 paired MRI–PET datasets including multiple tracers and acquisition sites. All regions showed excellent consistency (ICC $\geq$ 0.859, minimum threshold 0.75), with low variability.

Centiloid binary agreement was validated in 176 paired T1-weighted MRI and amyloid PET scans, with a kappa value of 0.82 meeting the acceptance criterion ($\kappa \geq 0.7$), indicating substantial agreement between Centiloid-based binary classification (using predefined cutoff Centiloid≥30) and expert visual interpretation. Also, the consistency with an FDA-cleared predicate device (K252496) showed good results (ICC=0.996, minimum threshold 0.6) and a proportion of subjects within a predefined range of ±10CL (95.45%). Meanwhile, repeatability/reproducibility was validated in 49 paired datasets with great consistency (≥0.997, minimum threshold 0.75)

All test results demonstrate that Neurophet SCALE PET achieves segmentation and quantification performance that is substantially equivalent to its FDA-cleared predicate devices. The device demonstrates consistent and reliable performance across diverse patient populations and imaging conditions, supporting its intended use.

3) Cybersecurity

• "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions", on September 27, 2023

9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

There are no significant differences between the subject, predicate device #1 (K221405) and predicate device #2(K252496) that would adversely affect the use of the product. It is substantially equivalent to these devices in indications for use and technology characteristics.

10. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, concludes that the Neurophet SCALE PET is substantially equivalent in safety and effectiveness to the predicate device as described herein.