January 29, 2026

Neurophet., Inc.
% Jonghyun Kim
CEO
Global Medical Standard Consulting Co., Ltd.
#612, De Riverwork Bldg. B
66, Cheongcho-Ro, Deogyang-Gu Goyang-Si,
Gyeonggi-Do, 10543
Republic Of Korea

Re: K252496
Trade/Device Name: Neurophet AQUA AD Plus
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: December 30, 2025
Received: December 30, 2025

Dear Jonghyun Kim:

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.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252496

Please provide the device trade name(s).

Neurophet AQUA AD Plus

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

[As Required by 21 CFR 807.92]

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

01/27/2026

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: Yerim Lee
- Telephone No.: 82-10-4240-6771
- Email Address: yrlee@neurophet.com

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

510(k) Number	K252496
Trade/Device/Model Name	Neurophet AQUA AD Plus
Device Classification Name	Automated Radiological Image Processing Software
Regulation Number	21 CFR 892.2050
Classification Product Code	QIH (primary), LLZ (subsequent)
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	K241098
Trade/Device/Model Name	NeuroQuant
Device Classification Name	Automated Radiological Image Processing Software
Regulation Number	892.2050
Classification Product Code	QIH (primary), LLZ (subsequent)
Device Class	Class II
510(k) Review Panel	Radiology

- **Predicate device #2**

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

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

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

Neurophet AQUA AD Plus is a software device intended for the automatic labeling of brain structures, visualization, and volumetric quantification of segmented brain regions and lesions, as well as standardized uptake value ratio (SUVR) quantification using MR and PET images. The volumetric outcomes are compared to normative reference data to support the evaluation of neurodegeneration and cognitive impairment.

The device is designed to assist physicians in clinical evaluation by streamlining the clinical workflow from patient registration through image analysis, analysis result archiving, and report generation using software-based functionalities. The device provides percentile-based results by comparing an individual's imaging-derived quantitative analysis results to reference populations. Percentile-based results are provided for reference only and are not intended to serve as a standalone basis for diagnostic decision-making. Clinical interpretation must be performed by qualified healthcare professionals.

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

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.

7. Technological Comparison [21 CFR 807.92(a)(6)]

Provided below is a table that compares technological characteristics of the Neurophet AQUA AD Plus and the predicate device

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

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
K Number	K252496	K241098	K221405	-
Manufacturer	NEUROPHET, Inc.	CorTechs Labs, Inc.	NEUROPHET, Inc.	-
Product Name	Neurophet AQUA AD Plus	NeuroQuant	SCALE PET	-
Product Code	QIH (primary), LLZ (subsequent)	QIH (primary), LLZ (subsequent)	LLZ	Identical.
Regulation Number	892.2050	892.2050	892.2050	Identical
510(k) Review Panel	Radiology	Radiology	Radiology	Identical
Indications for Use	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.	Automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric data may be compared to reference percentile data	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	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 radiotracer and disease combinations.	
Design and Incorporated Technology	• 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 indicate the degree of amyloid	• Automated measurement of brain tissue volumes and structures and lesions • Automatic segmentation and quantification of brain structures and lesions using a dynamic probabilistic neuroanatomical atlas, with age and gender specificity, based on the MR image intensity and static deep-learning technologies	• Automated measurement of brain tissue volumes and structures and lesions • Automatic segmentation and quantification of brain structures and lesions 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.	Similar

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
	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 Linux, Mac OS X and Windows.	Supports windows	Identical
Processing Architecture	Automated internal pipeline that performs: -artifact correction -segmentation -lesion quantification -volume calculation -SUVR calculation -Centiloid Scale calculation -report generation	Automated internal pipeline that performs: -artifact correction -segmentation -lesion quantification -volume calculation -report generation	Automated internal pipeline that performs: -artifact correction -segmentation -lesion quantification -volume calculation -SUVR calculation -report generation	Similar
Data Source	• MRI scanner: 3D T1 and T2 FLAIR, T2* GRE / SWI MRI • PET scanner: Amyloid PET • Neurophet AQUA AD Plus Supports DICOM format as input	• MRI scanner: 3D T1 and T2 FLAIR and T2* GRE / SWI MRI scans acquired with specified protocols • NeuroQuant Supports DICOM format as input	• MRI scanner: 3D T1-Weighted • PET scanner: Amyloid PET, FDG PET • SCALE PET Supports DICOM format as input	Similar
Output	• Provides volumetric measurements of brain structures and lesions • provides the capabilities to adjust image transparency and apply color mapping to	• Provides volumetric measurements of brain structures and lesions • Includes segmented color overlays and morphometric reports • Automatically	• Provides volumetric measurements of brain structures and lesions • provides the capabilities to adjust image transparency and apply color mapping to	Similar

	Proposed Device	Predicate Device #1	Predicate Device #2	Note
	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	compares results to reference percentile data and to prior scans when available • 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	
Safety	Automated quality control functions: -Tissue contrast check -Scan protocol verification -Atlas alignment check Results must be reviewed by a trained physician	Automated quality control functions: -Tissue contrast check -Scan protocol verification -Atlas alignment check Results must be reviewed by a trained physician	Automated quality control functions: -Tissue contrast check -Scan protocol verification -Atlas alignment check Results must be reviewed by a trained physician	Identical

The technological parameters of the Neurophet AQUA AD Plus 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 AQUA AD Plus 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 AQUA AD Plus was validated for its intended use and evaluated to determine substantial equivalence to the predicate devices. The device consists of multiple AI modules for automated segmentation and quantitative analysis of brain structures and lesions using MR and PET images. Performance characteristics were established through a series of independent tests on validation datasets that were separate from training data and reflected variability in scanner vendors, acquisition protocols, demographics, and clinical diagnoses, summarized as follows:

a) Training Data

The AI-based modules (T1-SegEngine, FLAIR-SegEngine, PET-Engine, ED-SegEngine, HEM-SegEngine) were trained using multi-center MRI and PET datasets collected from public repositories (e.g., ADNI, AIBL, PPMI) and institutional clinical sites. 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).
- A spectrum of clinical conditions relevant to the intended use, including clinically normal, mild cognitive impairment, and Alzheimer's disease, as well as patients with cerebrovascular and amyloid-related pathologies for lesion-segmentation modules.
- MRI acquired on major vendor platforms (GE, Siemens, Philips) at 1.5T and 3T using standard 3D T1-weighted, T2-FLAIR, GRE, and SWI protocols, and amyloid PET acquired on multiple PET systems with commonly used tracers (Amyvid, Neuraceq, Vizamyl).

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

b) Performance Test (summary of key quantitative results)

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

T1-SegEngine (T1-weighted structural MRI segmentation)

- For the T1-SegEngine, standalone accuracy evaluation was performed using 60 independent T1-weighted MRI cases, with segmentation performance assessed by comparison against expert manual segmentations using the Dice Similarity Coefficient (DSC). The predefined acceptance criteria for MRI segmentation accuracy, defined by the 95% confidence interval of the DSC, were set to [0.750, 0.850] for major cortical brain structures and [0.800, 0.900] for major subcortical brain structures. The evaluation results demonstrated a mean DSC of 0.83 ± 0.04 for cortical regions, corresponding to a 95% confidence interval of 0.82–0.84, and a mean DSC of 0.87 ± 0.03 for subcortical regions, corresponding to a 95% confidence interval of 0.86–0.88. Accordingly, the segmentation performance of the T1-SegEngine met the predefined acceptance criteria.

- Reproducibility: In 60 subjects with paired T1-weighted scans (120 scans total), the mean Average Volume Difference Percentage (AVDP) was 2.50 ± 0.93% (95% CI: 2.26–2.74) for subcortical regions and 1.79 ± 0.74% (95% CI: 1.60–1.98) for cortical regions, within the predefined equivalence range of 1.0–5.0%.

FLAIR-SegEngine (T2-FLAIR hyperintensity segmentation)

- Accuracy: In 136 independent T2-FLAIR cases, the overall mean DSC for lesion segmentation was 0.90 ± 0.04 (95% CI: 0.89–0.91), exceeding the predefined acceptance criterion of mean DSC ≥ 0.80.

- Reproducibility: Paired T2-FLAIR scans showed a mean AVDP of 0.99 ± 0.66% and a mean absolute lesion volume difference of 0.08 ± 0.06 cc, both well within pre-specified equivalence criteria (absolute difference < 0.25 cc and mean AVDP < 2.5%).

PET-Engine (SUVR and Centiloid quantification)

- SUVR accuracy: In 30 paired MRI–PET datasets including multiple tracers and sites, SUVR values showed excellent agreement with an FDA-cleared reference product (K221405), with intraclass correlation coefficients (ICC) ≥ 0.993 across seven Alzheimer's-relevant regions, exceeding the predefined minimum threshold of 0.60.

- Centiloid classification: In 176 paired T1-weighted MRI and amyloid PET scans from ADNI and AIBL, Centiloid-based amyloid positivity classifications (cutoff: 30) achieved kappa values that met or exceeded the acceptance criterion of $\kappa \geq 0.70$, indicating substantial agreement with consensus expert visual reads.

ED-SegEngine (edema-like T2-FLAIR hyperintensity segmentation)

- Accuracy: In 100 T2-FLAIR scans collected from U.S. and U.K. clinical sites, the mean DSC versus expert manual segmentations was 0.91 ± 0.09 (95% CI: 0.89–0.93), exceeding a benchmark threshold of DSC ≥ 0.70 and demonstrating robust performance across diverse patient populations and imaging protocols.

HEM-SegEngine (GRE/SWI hypointense lesion segmentation)

- Accuracy: In 106 GRE/SWI scans from U.S. clinical sites, the HEM-SegEngine achieved a median F1-score (DSC) of 0.860 (95% CI: 0.824–0.902), surpassing the required

benchmark of F1-score ≥ 0.60 and supporting robust performance for hypointense lesion segmentation across varying sequences and demographics.

Collectively, these performance tests confirm that Neurophet AQUA AD Plus achieves segmentation and quantification performance that meets or exceeds predicate-based acceptance thresholds and demonstrates consistent results across scanners, protocols, and patient subgroups, supporting its safe and effective use within the proposed indications.

c) Validation of AI-based Segmentation and Quantification Modules

To provide additional transparency for the AI-based components, the validation of each module is summarized in terms of the datasets, reference standards, and evaluation methods applied.

Dataset design and independence

- For all modules, validation datasets were fully independent from training datasets at the subject level. No subjects or manual labels used for training were reused for validation, and validation data were drawn from distinct sites and/or repositories where applicable.

Demographics and study subgroups

- Validation cohorts covered adult subjects across a broad age range (approximately 40–80+ years), with both females and males represented.
- Racial/ethnic composition included White, Asian, Black, and African American subjects, depending on the underlying public and institutional datasets.
- Clinical subgroups included clinically normal, mild cognitive impairment, and Alzheimer's disease for structural, FLAIR, and PET modules, and cerebrovascular/amyloid-related pathologies for ED- and HEM-SegEngines, capturing relevant disease spectra and potential confounders.

Equipment and acquisition protocols

- MRI validation data spanned multiple vendors (GE, Siemens, Philips), field strengths (1.5T and 3T), and protocol variations, including differences in voxel size, slice thickness, and TR/TE/TI across T1-weighted, T2-FLAIR, GRE, and SWI sequences.
- PET validation data included multiple PET scanners and amyloid tracers (Amyvid, Neuraceq, Vizamyl) with clinically representative acquisition parameters.

Reference standard ("truthing") process

- For structural and lesion segmentation modules (T1-, FLAIR-, ED-, HEM-SegEngines), reference segmentations were generated by subspecialty-trained neuroradiologists using predefined anatomical and lesion-labeling criteria, with consensus/adjudication procedures and internal quality control to ensure consistency.
- For SUVR quantification, reference values were obtained from an FDA-cleared comparison tool. For Centiloid classification, reference labels were derived from consensus expert visual interpretation using established amyloid PET reading criteria.

Within this framework, the test statistics and acceptance criteria summarized in section 2.b) were applied to each AI-based module, and all modules met their predefined thresholds. This supports the adequacy of the validation strategy and the appropriateness of the characterized performance for the intended quantitative, non-interpretive use of Neurophet AQUA AD Plus.

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 and reference devices, K241098 and K221405 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 AQUA AD Plus is substantially equivalent in safety and effectiveness to the predicate device as described herein.