May 15, 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: K261273
Trade/Device Name: Neurophet AQUA
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 17, 2026
Received: April 17, 2026

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 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,

Digitally signed by Michael D. O'hara -S
Date: 2026.05.15 15:42:55 -04'00'

Michael 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

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.	K261273

Please provide the device trade name(s).

Neurophet AQUA

Please provide your Indications for Use below.

Neurophet AQUA is intended for 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

K261273

510(k) Summary

[As Required by 21 CFR 807.92]

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

04.02, 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.: +82-2-6954-7971
- Email Address: ra@neurophet.com
- Registration No.: TBD

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

510(k) Number	K261273
Trade/Device/Model Name	Neurophet AQUA
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	K242215
Trade/Device/Model Name	Neurophet AQUA (V3.1)
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

This predicate device have not been subject to a design-related recall.

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

Neurophet AQUA is designed for aiding physicians to make a medical decision for neurodegenerative diseases. The system streamlines clinical workflow from patient registration to analysis result archival and report generation with software-based features for analyzing magnetic resonance imaging data.

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

Neurophet AQUA is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. Volumetric data 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 and the predicate device

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

	Proposed Device	Predicate Device	Note
K Number	TBD	K242215	-
Manufacturer	NEUROPHET, Inc.	NEUROPHET, Inc.	-
Product Name	Neurophet AQUA	Neurophet AQUA V3.1	-
Product Code	QIH (primary), LLZ (subsequent)	QIH (primary), LLZ (subsequent)	Identical.
Regulation Number	892.2050	892.2050	Identical
510(k) Review Panel	Radiology	Radiology	Identical
Indications for Use	Neurophet AQUA is intended for 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 AQUA is intended for 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.	Identical
Target Anatomical Sites	Brain	Brain	Identical
Design and Incorporated Technology	• Automated measurement of brain tissue volumes, structures, and lesions • Automatic segmentation and quantification of brain structures using deep learning • Supports both on-premise and off-premise (cloud-based) deployment for analysis	• Automated measurement of brain tissue volumes, structures, and lesions • Automatic segmentation and quantification of brain structures using deep learning	Similar
Physical characteristics	• Software package • Operates on off-the-shelf hardware (multiple	• Software package • Operates on off-the-shelf hardware (multiple	Identical

	Proposed Device	Predicate Device	Note
	vendors)	vendors)	
Operating System	Windows	Windows	Identical
Processing Architecture	Automated internal pipeline that performs: -segmentation -volume calculation -lesion quantification -report generation	Automated internal pipeline that performs: -segmentation -volume calculation -lesion quantification -report generation	Identical
Data Source	• MRI scanner: 3D T1 and FLAIR MRI scans acquired with specified protocols • Supports DICOM format as input	• MRI scanner: 3D T1 and FLAIR MRI scans acquired with specified protocols • Supports DICOM format as input	Identical
Output	• Provides volumetric measurements of brain structures and lesions • Includes segmented color overlays and morphometric reports • Automatically 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	• Provides volumetric measurements of brain structures and lesions • Includes segmented color overlays and morphometric reports • Automatically 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	Identical
Safety	Automated quality control functions -Image artifact check -Scan protocol verification Results must be reviewed by a trained physician	Automated quality control functions -Image artifact check -Scan protocol verification Results must be reviewed by a trained physician	Identical

The technological parameters of the Neurophet AQUA 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. Summary of Non-Clinical Performance Testing

1) performance

No additional performance testing was conducted for Neurophet AQUA, because the modifications implemented for this Special 510(k) do not change the intended use or performance characteristics of the device compared to the predicate device Neurophet AQUA (V3.1, K242215). Neurophet confirmed, through design verification and validation performed under the company's design control procedures, that the subject device meets the same performance specifications as the predicate device and that the modifications do not raise new questions of safety or effectiveness.

2) Software

The Neurophet AQUA contains basic 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.

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, K242215 that would adversely affect the use of the product. It is substantially equivalent to this device 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 is substantially equivalent in safety and effectiveness to the predicate device as described herein.