October 4, 2023

VUNO Inc.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. Ste. 160
Irvine, CA 92612

Re: K231398
Trade/Device Name: VUNO Med-DeepBrain
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: August 31, 2023
Received: September 5, 2023

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 (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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231398

Device Name
VUNO Med-DeepBrain

Indications for Use *(Describe)*

The VUNO Med-DeepBrain is intended for automatic labeling, quantification and visualization of segmentable brain structures from a set of MR images. The software is intended to automate the current manual process of identifying, labeling and quantifying segmentable brain structures identified on MR images.
The users are trained healthcare professionals who work with medical imaging.
The product is used in an office-like environment.

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

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

1. **Date:** 10/3/2023

2. **Applicant / Submitter**

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

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

VUNO Med-DeepBrain

5. **Common Name:**

Medical Image Processing Software

6. **Classification:**

System, Image Processing, Radiological Picture Archiving and Communications System (21CFR 892.2050, Product code QIH, LLZ, Class 2, Radiology)

7. **Device Description:**

The VUNO Med-DeepBrain provides brain structural information based on the brain MR image. Input images for analysis are 3D T1 weighted brain MR images and 2D T2 flair brain MR images. Once the recommended images are uploaded, automated brain segmentation is

performed and provides volumetric data of brain regions. It is displayed in the viewer with a color map.
VUNO Med-DeepBrain is intended for automatic labeling, visualization, and volumetric quantification of segmentable brain structures and lesions from a set of MR images. It takes a 3D T1 MR image as input and gives segmented brain structures and lesions, and volumetric quantification. The user interface is provided for the visualization. The segmented structures are displayed as a color map and the user can view regions by selecting the name of the region. The 2D T2 Flair MR image is taken for lesion quantification. In addition, the uploaded image can be compared to the normative percentile and prior images when applicable. The user can download and print the result in a report format.
The data can be received and sent through the Picture Archive and Communications Systems (PACS) using the DICOM protocol.

8. Indication for use:

The VUNO Med-DeepBrain is intended for automatic labeling, quantification and visualization of segmentable brain structures from a set of MR images. The software is intended to automate the current manual process of identifying, labeling and quantifying segmentable brain structures identified on MR images.
The users are trained healthcare professionals who work with medical imaging.
The product is used in an office-like environment.

9. Predicate Device:

cNeuro® cMRI(K171328) by Combinostics OY

10. Substantial Equivalence:

	Subject Device	**Predicate Device**
Trade name	VUNO Med-DeepBrain	cNeuro cMRI
Manufacturer	VUNO Inc.	Combinostics OY
510k number	K231398	K171328
Classification	Class II, LLZ, 21 CFR 892.2050	Clss II, LLZ, 21 CFR 892.2050
Indications for Use	The VUNO Med-DeepBrain is intended for automatic labeling, quantification and visualization of segmentable brain structures from a set of MR images. The software is intended to automate the current manual process of identifying, labeling	cNeuro cMRI is intended for automatic labeling, quantification and visualization of segmentable brain structures from a set of MR images. The software is intended to automate the current manual process of identifying, labeling and quantifying

	Subject Device	Predicate Device
	and quantifying segmentable brain structures identified on MR images. The users are trained healthcare professionals who work with medical imaging. The product is used in an office-like environment.	segmentable brain structures identified on MR images. The users are trained healthcare professionals who work with medical imaging. The product is used in an office-like environment.
Deployment	Cloud based	Cloud based

The comparison table shows the description of the subject device and predicate device in each aspect. The comparison rationale and gap between the subject device and the predicate device are provided below.

- Indications for use

The indications for use are the same. Both are intended to provide brain structural identification and quantification volumes.

- Design and Incorporated Technology

The design and incorporated technology are equivalent. Both devices are software that takes 3D T1 MR images at 1.5T and 3T as input and automatically offers measurement of brain tissue volumes and structures and lesions.
The algorithm used in both software is based on the machine learning technique in which the device learns the characteristics of brain MR images from a large dataset. However, there are several differences in specific learning techniques based on machine learning. The predicate used a multi-atlas segmentation, while the subject device is based on deep learning.
Both devices have the same mechanism by which MR images are used as inputs and the segmented brain region and segmentation result is provided as output. And the test performance proves the efficiency even in minor differences in algorithm.

- Deployment

The deployment characteristics are the same. Both are cloud-based software package that is installed on the user's hardware.

- Environment

The environment is the same. Both are operated in office-like environment.

- Processing Architecture

The processing architecture is the same. Both have the same process which is, when the brain MR images come in, the image is pre-processed for the adequate format.
The predicate device is pre-processed with bias-field correction and skull stripping(brain extraction) while the subject device performs size resampling, rigid registration, and bias-field correction(optional) for the T1 MR image and rigid registration and brain extraction for

the T2 MR image. The difference is that one is performed by default and the other is optional. However, both support this function.
Quality control methods also vary. The predicate device performs quality control with the user's check, but the subject device removes outliers in a post-processing step and allows the user to review and hidden areas if inappropriate. But both have the functionality to control the output.
Both devices automatically provide segmentation, lesion quantification, and volume calculation and generates a report.
The differences have no impact on safety and effectiveness.

- Data source

The data source is the same. Both take T1 weighted images and T2 flair images as input for the labeling and volumetric quantification of brain segmentation.

- Output

The output is similar. Both the subject and predicate device provides a color map of segmented regions, white matter hyperintensities from T2 FLAIR MR images, and morphometric reports, and integrates with the Picture Archive and Communications Systems(PACS).
Similarities with differences are as follows.
Subject device and predicate device segments cortical and subcortical structures from MRI T1 images. The predicate provides 133 brain structures, but the subject device provides 104 structures including two vessels. Brain structures can be parcellated into various numbers, though, it is important to include neuroanatomically significant areas. The subject device is based on the region parcellation principle of FreeSurfer, which is a silver standard. So, the subject device provides clinically important brain regions, and the basis is subsequently equivalent to the predicate device. Minor differences do not raise safety problems.
Both provide a color map on MR T1 images highlighting regions where the patient is smaller than the reference data. The predicate device provides a color map of the gray matter concentration, while the subject device provides every region including gray matter. It is a visual complement to the quantitative data.
The differences do not affect the safety and effectiveness of the device.

- Safety

Both devices are safe, but there is a difference due to the technological characteristic. The predicate device has an automated atlas alignment check that is not required for the subject device. Instead, the subject device is post-processed with an outlier removal to adjust the output. Both have tissue contrast checks and scan protocol verification. And the results should be reviewed by a trained physician.

VUNO Med-DeepBrain is intended for automatic labeling, visualization, and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Brain structural information is considered useful in brain diagnosis screening tools. The intended use is the same as the predicate device. And while other comparable characteristics are considered to be the same, the segmentation algorithm has a difference.

Mainly the algorithm used for the segmentation is different. The predicate device used a machine learning technique while the subject device is built upon a deep learning model. The underlying mechanism is the same that the model learns the extracted feature from the image and automatically provides segmentation of the brain MR image.
Meanwhile, there are minor differences also.
The predicate device is pre-processed with bias-field correction, but the subject device is available as an option. And the predicate device has a quality control function by the user's check, but the subject device is post-processed with an outlier remover and the user can turn off the regions.
In addition, the number of segmented areas is different between the two devices. Though, the output region of the subject device contains neuroanatomically important regions.
Despite the differences, the subject device shows reliable output in the performance test of segmentation accuracy and reproducibility.
In conclusion, the subject device is substantially equivalent to the predicate device. And no additional risks are presented in the perspective of safety and effectiveness.

11. Nonclinical Tests

Nonclinical tests were conducted to test the functionality of the subject device.

Verification and Validation
VUNO Med-DeepBrain is designed safely and effectively throughout the product lifecycle in accordance with the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (May 11, 2005)".
VUNO Med-DeepBrain is considered as a "Moderate" level of concern and software validation such as unit test, integration test, and system test is performed accordingly.
VUNO Med-DeepBrain is a cyber device and the risks associated with cybersecurity are identified and addressed. The device meets the requirement under the FDA Guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (October 2, 2014)".

12. Performance Data:

Segmentation Accuracy Test and Reproducibility Test were conducted to establish the performance and reliability characteristics of the subject device.
Segmentation accuracy is measured by Dice Similarity Coefficient(DSC) score compared to expert. The acceptance criteria are an average DSC score of 0.80 in brain regions and White Matter Hyperintensities(WMH) regions as referred to in the literature. Whole brain regions including cortical and subcortical as well as WMH regions exceeded the criteria.
In addition, volume errors between manual segmentation and device output are analyzed. The average relative volume errors of the Hippocampus, Thalamus, and Lateral ventricle, which are major regions, were 0.03 mm^3, 0.01 mm^3, and 0.01 mm^3, respectively. The average absolute volume errors for these areas were 207mm^3, 140 mm^3, and 377 mm^3, respectively.

Test-retest reproducibility is also measured by the intraclass correlation coefficient. The acceptance criteria are set to 0.965 for brain structures and 0.988 for WMH. The result exceeded criteria which mean excellent reliability.
The device passed all of the tests based on pre-determined Pass/Fail criteria.

13. Clinical tests

No clinical test was required to demonstrate substantial equivalence.

14. Summary of nonclinical and clinical tests

The subject device is verified and validated to show its functionality and security.
For performance, Segmentation Accuracy Test and Reproducibility Test are conducted and passed the acceptance criteria.
Test results demonstrate that the VUNO Med-DeepBrain is safe and effective similar to the predicate device.

15. 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 performance test. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.