CorTechs Labs, Inc.
Kora Marinkovic
VP of Quality and Regulatory Affairs
5060 Shoreham Place CA Ste 240
San Diego, California 92122

August 22, 2024

Re: K241098
Trade/Device Name: NeuroQuant
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: July 22, 2024
Received: July 22, 2024

Dear Kora Marinkovic:

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,

Digitally signed by
Douglas W. Fletcher -S

for
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)*

K241098

Device Name

NeuroQuant

Indications for Use *(Describe)*

NeuroQuant is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric measurements may be compared to reference percentile data.

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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Cortechs.ai

5060 Shoreham Place
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510(k) Summary: NeuroQuant

1. Submitter

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Date Prepared:	8/21/2024

2. Device

Device Trade Name:	NeuroQuant
Common Name:	Medical Image Processing Software
Classification Name:	System, Image Processing, Radiological
Regulation Number:	21 CFR 892.2050
Regulation Description:	Medical image management and processing system
Product Code:	QIH, LLZ
Classification Panel:	Radiology

3. Predicate Device

Device:	NeuroQuant
510(k) Number	K170981
Manufacturer	CorTechs Labs, Inc
Product Code:	LLZ

4. Device Description

NeuroQuant is a fully automated MR imaging post-processing software medical device that provides automatic labeling, visualization, and volumetric quantification of brain structures and lesions from a set of MR images and returns segmented images and morphometric reports.

NeuroQuant provides morphometric measurements of brain structures based on a 3D T1 MRI series. The optional use of the T2 FLAIR MR series and T2* GRE/SWI series allows for additional quantification of T2 FLAIR hyperintense lesions and T2* GRE/SWI hypointense lesions.

The device is used by medical professionals in imaging centers, hospitals, and other healthcare facilities as well as by clinical researchers. When used clinically, the output must be reviewed by a radiologist or neuroradiologist. The results are typically forwarded to the referring physician, most commonly a neurologist. The device is a “Prescription Device” and is not intended to be used by patients or other untrained individuals.

From a workflow perspective, the device is packaged as a computing appliance that is capable of supporting DICOM standard input and output. NeuroQuant supports data from all major MRI manufacturers and a variety of field strengths. For best results, scans should be acquired using specified protocols provided by CorTechs Labs.

As part of processing, the data is corrected by NeuroQuant for image acquisition artifacts, including gradient nonlinearities and bias field inhomogeneity, to improve overall image quality.

Next, image baseline intensity levels for gray and white matter are identified and corrected for scanner variability. The scan is then aligned with the internal anatomical atlas by a series of transformations. Probabilistic methods and neural network models are then used to label each voxel with an anatomical structure based on location and signal intensities.

Output of the software provides values as numerical volumes, and images of derived data as grayscale intensity maps and as color overlays on top of the anatomical image. The outputs are provided in standard DICOM format as image series and reports that can be displayed on many commercial DICOM workstations.

The software is designed without the need for a user interface after installation. Any processing errors are reported either in the output series error report or system log files.

The software can provide data on age and gender-matched normative percentiles. The default reference percentile data for NeuroQuant comprises normal population data.

The device provides DICOM Storage capabilities to receive MRI series in DICOM format from an external source, such as an MRI scanner or PACS server. The device provides transient data storage only. If additional scans from other time points are available, the software can perform change analysis.

5. Intended Use / Indications for Use

NeuroQuant is intended for automatic labeling, visualization, and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric measurements may be compared to reference percentile data.

6. Comparison to Predicate Device

Summary Comparison Table for the device and predicate device (K170981):

Device Name	NeuroQuant (Predicate, K170981)	**NeuroQuant (Current Submission)**
Classification	Class II	Class II
Product Code	LLZ	QIH, LLZ
Indications for Use	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	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
Design and Incorporated Technology	• Automated measurement of brain tissue volumes and structures and lesions • Automatic segmentation and quantification of brain structures using a dynamic probabilistic neuroanatomical atlas, with age and gender specificity, based on the MR image intensity	• 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
Physical characteristics	• Software package • Operates on off-the-shelf hardware (multiple vendors)	• Software package • Operates on off-the-shelf hardware (multiple vendors)
Operating System	Supports Linux, Mac OS X and Windows.	Supports Linux, Mac OS X and Windows.
Processing Architecture	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 - report generation
Data Source	• MRI scanner: 3D T1 and T2 FLAIR MRI scans acquired with specified protocols • NeuroQuant 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
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
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

Similarities between NeuroQuant and NeuroQuant (Predicate K170981) software

- Both devices are post-processing software applications for analysis of MR imaging data
- Both devices have the ability to perform volumetric quantification of MR imaging data
- Both devices offer the ability to compare medical images and/or multiple time points
- Both enable visualization of information that would otherwise have to be visually compared disjointedly
- Both devices have the ability to report derived imaging metrics
- Both devices are intended for use on anatomical MR images to provide volumetric quantification of brain structures.

Differences between NeuroQuant and NeuroQuant (Predicate K170981) software

- Addition of T2* GRE / SWI MRI as a data source
- Addition of static deep-learning technologies

7. Verification and Validation

NeuroQuant software was tested in accordance with CorTechs verification and validation (V&V) processes. All product and engineering specifications were verified and validated. Software V&V testing was conducted, and documentation was provided at the documentation level as recommended for premarket submissions for software devices in the FDA's "Content of Premarket Submission for Device Software Functions" guidance document.

Verification and Validation tests have been performed to address the intended use, the technological characteristics claims, requirement specifications, and the risk management results.

The V&V and performance data were provided in support of safety and effectiveness for the substantial equivalence determination.

NeuroQuant verification and validation testing included:

1) objective unit testing comparing the software-derived values to the known ground truth values,

2) system testing to verify that the RGB Overlays and Reports are correctly generated when compatible anatomical images are input to NeuroQuant, and

3) Clinical validation testing to ensure that the RGB Overlays and Reports are correct, meet clinical expectations, and are safe and effective.

Testing performed demonstrated that NeuroQuant meets all defined functionality requirements and performance claims.

The test results demonstrate that NeuroQuant complies with the international and FDA-recognized consensus standards and FDA guidance documents listed in the Premarket Submission, meets the acceptance criteria, and is adequate for its intended use and specifications.

8. Performance Testing

In this NeuroQuant software, three deep-learning models were included: Brain Segmentation; FLAIR Lesion Segmentation; and MCH Segmentation.

Performance testing was designed specifically to ensure the robustness, generalizability, and accuracy of the models, as described below.

Brain Segmentation Model

The NeuroQuant Brain Segmentation Model was evaluated using the Dice Similarity Coefficient (DSC) as the primary performance metric. The model's performance was assessed against the predicate device and meets the acceptance criteria for accuracy and reproducibility.

The model was trained on a diverse dataset of 1,473 3D T1-weighted MRI series from over 16 institutions, encompassing a wide range of scanner protocols, field strengths, manufacturers, and scanner models. The test set comprised 30 patients with a gender distribution of 47% female and 53% male, aged 20-40 years. By utilizing a separate dataset for testing, independence between training and test data was ensured. Both datasets were curated to represent the diverse patient population across the United States, with no exclusion criteria based on race or ethnicity.

FLAIR Segmentation Model

The NeuroQuant FLAIR Lesion Segmentation Model demonstrated strong performance, achieving a mean Dice Similarity Coefficient (DSC) of 0.70 with a standard deviation of 0.14, surpassing the acceptance criteria in comparison to the predicate device of mean DSC ≥ 0.50 and standard deviation ≤ 0.18. This model was specifically designed to identify FLAIR hyperintensities, which may be caused by conditions such as multiple sclerosis, microvascular ischemic disease, or vasogenic edema.

The model was developed using a training set of 340 T1 and FLAIR MRI series from 22 institutions, incorporating various scan protocols, MRI scanner models, and field strengths. The test set comprised 63 patients, with a gender distribution of 67% female and 33% male, ranging in age from 25 to 87 years. Test data was acquired across Philips, GE, and Siemens scanners. To ensure independence between training and test data, a stratified sampling method was employed for an 80%/20% train/test split. Both datasets were curated to represent the diverse patient population across the United States, with no exclusion criteria based on race or ethnicity.

MCH Detection Model

The MCH Detection Model in NeuroQuant exhibited robust performance, achieving a median F1 Score of 0.60, which exceeded the acceptance criteria of ≥ 0.51. This model was developed to detect cerebral hypointensities associated with blood products, such as cerebral microbleeds and superficial siderosis, which may be caused by conditions including vascular disease, cerebral amyloid angiopathy (CAA), and anti-amyloid therapy (ARIA-H).

The model was trained on 463 2D T2*GRE/SWI MRI series from over 68 institutions, encompassing a wide range of scanner protocols, manufacturers, and models. The test set included 117 patients, with a gender distribution of 42% female and 58% male, spanning ages from 21 to over 81 years. The racial distribution of the combined dataset was 87.8% White, 2.9%

Black, 1.8% More than One, 1.5% Asian, and 5.7% No Data. Test data was acquired using Philips, GE, and Siemens scanners. Independence between training and test data was ensured through a stratified sampling method for an 80%/20% train/test split, with a power analysis conducted to determine the minimum sample size required for statistical significance. Both datasets were curated to represent the diverse patient population across the United States, with no exclusion criteria based on race or ethnicity.

9. Conclusions

The testing summarized above shows that the device is as safe, as effective and performs as well as the predicate device, and as well as gold standard - computer-aided expert manual segmentation.

By virtue of its physical characteristics and intended use, NeuroQuant is substantially equivalent to its predicate device, and its technological improvements do not raise new questions of safety and effectiveness.