DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 7, 2017

CorTechs Labs, Inc
Kora Marinkovic
Director of Quality and Regulatory Affairs
4690 Executive Drive, Suite 250
San Diego, CA 92121

Re: K170981
Trade/Device Name: NeuroQuant
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 9, 2017
Received: August 11, 2017

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 (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. 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.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170981

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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510(k) Summary: NeuroQuant®

1. Submitter

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Date Prepared:	8/4/2017

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:	Picture archiving and communications system
Product Code:	LLZ
Classification Panel:	Radiology

3. Predicate Device

Device:	NeuroQuant™
510(k) Number	K061855
Manufacturer	CorTechs Labs, Inc
Product Code:	LLZ

4. Device Description

NeuroQuant is a fully automated MR imaging post-processing medical device software 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. The resulting output is provided in a standard DICOM format as additional MR series with segmented color overlays and morphometric reports that can be displayed on third-party DICOM workstations and Picture Archive and Communications Systems (PACS). The high throughput capability makes the software suitable for use in both clinical trial research and routine patient care as a support tool for clinicians in assessment of structural MRIs.

NeuroQuant provides morphometric measurements based on 3D T1 MRI series. The output of the software includes volumes that have been annotated with color overlays, with each color representing a particular segmented region, and morphometric reports that provide comparison of measured volumes to age and gender-matched reference percentile data. In addition, the adjunctive use of the T2 FLAIR MR series allows for improved identification of some brain abnormalities such as lesions, which are often associated with T2 FLAIR hyperintensities.

The NeuroQuant processing architecture includes a proprietary automated internal pipeline that performs artifact correction, atlas-based segmentation, volume calculation and report generation.

Additionally, automated safety measures include automated quality control functions, such as tissue contrast check, atlas alignment check and scan protocol verification, which validate that the imaging protocols adhere to system requirements.

From a workflow perspective, NeuroQuant is packaged as a computing appliance that is capable of supporting DICOM file transfer for input and output of results.

5. Intended Use

NeuroQuant® is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. It is intended to automate the manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on MR images.

6. Comparison to Predicate Device

Summary Comparison Table for the device and predicate device (K061855):

	CorTechs Labs, Inc	CorTechs Labs, Inc
Device Name	**NeuroQuant™ V1.0**	**NeuroQuant® V2.2**
510(k) No	K061855	N/A
Regulation No	21 CFR 892.2050	21 CFR 892.2050
Regulation Description	"Picture archiving and communications system"	"Picture archiving and communications system"

Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological
Classification	Class II	Class II
Product Code	LLZ	LLZ
Indications for Use	Automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images, intended to automate the current manual process of identifying, labeling and quantifying the volume of segmentable brain structures identified on MR images	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 • Automatic segmentation and quantification of brain structures using a probabilistic neuroanatomical atlas based on the MR image intensity	• 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
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 and Mac OS X	Supports Linux, Mac OS X and Windows.
Processing Architecture	Automated internal pipeline that performs: - artifact correction - segmentation - volume calculation - report generation	Automated internal pipeline that performs: - artifact correction - segmentation - lesion quantification - volume calculation - report generation
Data Source	• MRI scanner: 3D T1 MRI scans acquired with specified protocols • NeuroQuant Supports DICOM format as input	• MRI scanner: 3D T1 MRI scans acquired with specified protocols • NeuroQuant Supports DICOM format as input
Output	▪ Provides volumetric measurements of brain structures ▪ 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

NeuroQuant is functionally similar and improved from a previous 510(k) market-cleared CorTechs Labs NeuroQuant software device (NeuroQuant K061855).

Both devices have same intended use and basic design and similar operating principle.

Both systems use clinical MR brain scans as input and automatically identify and measure volumes of brain structures. Both systems provide morphometric measurements based on 3D T1 MRI series. The resulting output is provided in a standard DICOM format as additional MR series that can be displayed on third-party DICOM workstations and PACS.

Both systems produce similar reports. The output includes volumes that have been annotated with color overlays, with each color representing a particular segmented region, and morphometric reports that provide comparison of measured volumes to reference percentile data.

They utilize the same automated safety measures and have similar processing architecture.

Both devices are DICOM compatible and operate on off-the-shelf hardware.

Both systems are used by medical professionals, such as radiologists, neurologists and neuroradiologists, as well as by clinical researchers, as a support tool in assessment of structural MRIs.

7. Performance Testing

NeuroQuant performance was evaluated by comparing segmentation accuracy with expert manual segmentations and by measuring segmentation reproducibility between same subject scans. The system yields reproducible results that are well correlated with computer-aided expert manual segmentations.

NeuroQuant's segmentation accuracy compared to expert manual segmentations of 3D T1 MRI scans was evaluated using Dice's coefficient metric. For major subcortical brain structures Dice's coefficients are in the range of 80-90% and for major cortical regions are in the range of 75-85%. For lesion segmentations evaluated separately using 3D T1 and T2 FLAIR MRI scan pairs of subjects with brain lesions, Dice's coefficient exceeds 80%.

Brain structure segmentation reproducibility of repeated 3D T1 MRI scans for same subjects was evaluated by using the percentage absolute volume differences. The mean percentage absolute volume differences for all major subcortical structures were in the range1-5%. Brain lesion segmentation reproducibility was evaluated separately using 3D T1 and T2 FLAIR MRI repeated scan pairs of subjects with brain lesions. The mean absolute lesion volume difference was less than 0.25cc, while the mean percentage lesion absolute volume difference was less than 2.5%.

8. Conclusions

The performance testing presented 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 the 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.