CorticoMetrics LLC
% Mr. Nick Schmansky
Co-Founder, CEO
128 Granite Street
ROCKPORT MA 01966

September 30, 2020

Re: K192051
Trade/Device Name: THINQ
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 26, 2020
Received: August 31, 2020

Dear Mr. Schmansky:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192051

Device Name
THINQ

Indications for Use *(Describe)*
THINQ is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures 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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K192051

CorticoMetrics

THINQ™

510(k) Summary

CorticoMetrics, LLC

August 22, 2020

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

1 Submitter

Name	CorticoMetrics, LLC
Address	128 Granite St., Rockport MA 01966 USA
Contact Person	Nick Schmansky
Telephone Number	617-329-5042
Fax Number	none
Email	nicks@corticometrics.com
Date Prepared	August 22, 2020

2 Device

Device Trade Name	THINQ™
Common Name	Medical Imaging Processing Software
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR §892.2050
Regulation Description	Picture archiving and communications system
Regulatory Class	Class II
Product Classification Code	LLZ
Classification Panel	Radiology

3 Predicate Device

Device	NeuroQuant
510(k) Number	K170981
Manufacturer	CorTechs Labs, Inc.
Common Name	Medical Imaging Processing Software
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR §892.2050
Regulation Description	Picture archiving and communications system
Regulatory Class	Class II
Product Classification Code	LLZ
Classification Panel	Radiology

4 Device Description

THINQ™ is a software-only, non-interactive, medical device for quantitative imaging, accepting as input 3D T1-weighted MRI scan data of the human head. THINQ™ produces as output a quantitative neuromorphometry report in PDF format. The report contains morphometric (volume) measurements and visualizations of various structures in the brain, and compares these measures to age and gender-matched reference percentile data. The report includes images of the brain with color-coded segmentations, as well as plots showing how measurements compare to reference data. Additionally, in order to visually confirm the accuracy of the results, three segmentation overlays are created in DICOM-JPEG format; one in each anatomical plane: sagittal, coronal and axial.

The THINQ™ processing pipeline performs an atlas-based segmentation of brain structures followed by measurement of those structures and a comparison to a reference dataset. The pipeline includes automated QA checks on the input DICOM 3D T1 MRI series to ensure adherence to imaging sequence requirements, checks on the data elements generated during the processing pipeline, and usage of a classifier to filter potentially incorrect reports due to corrupted image input.

THINQ™ is packaged as a container, for deployment and operation in a high-performance computing environment within a clinical workflow.

5 Intended Use

THINQ™ 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 of Technological Characteristics with the Predicate Device

	Subject Device	**Predicate Device**
Device	**THINQ™**	**NeuroQuant v2.2**
510(k) Number	K192051	K170981
Regulation Number	21 CFR §892.2050	21 CFR §892.2050
Regulation Description	Picture archiving and communications system	Picture archiving and communications system

	Subject Device	**Predicate Device**
Device:	**THINQ™**	**NeuroQuant v2.2**
Classification Name	System, Image Processing, Radiological	System, Image Processing, Radiological
Classification:	Class II	Class II
Product Code:	LLZ	LLZ
Indications for Use	THINQ™ is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. Volumetric measurements may be compared to reference percentile data.	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.
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	Supports Linux, Mac OS X and Windows
Deployment:	Container installation	Cloud based or installed
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 • THINQ supports DICOM format as input	• MRI scanner: 3D T1 MRI scans acquired with specified protocols • NeuroQuant supports DICOM format as input

	Subject Device	Predicate Device
Device:	**THINQ™**	**NeuroQuant v2.2**
Output	• Provides volumetric measurements of brain structures • Includes segmented color overlays and morphometric reports • Automatically compares results to reference percentile data • Report output is PDF file format • Outputs segmentation results as overlay in DICOM Encapsulated JPEG format allowing display on DICOM workstations and Picture Archive and Communications System	• 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: • Scan sequence (protocol) checks • Atlas alignment checks • Cortical surface checks • Result validity checks • 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

7 Performance Data

THINQ™ was designed, developed and tested in accordance with the following process standards:

- 21 CFR part 820 - Quality System Regulation / Medical Device Good Manufacturing Practices
- ISO 13485:2016 – Medical devices – Quality management systems
- ISO 14971:2007 – Medical devices – Application of risk management to medical devices
- ISO 62304:2006 – Medical device software – Software life-cycle processes
- ISO 62366-1:2015 – Medical devices – Part 1: Application of usability engineering to medical devices

Validation of THINQ included performance testing for accuracy, where comparisons were made to expert-labeled brain images, and reproducibility, where test-retest image data was used. The accuracy of the reference population model was validated against statistical tests of normality using both subject test data expected to align within the reference ranges, as well as subjects with neurological disorders where affected brain structures are known to lie outside

the reference ranges. A literature review of neuroimaging publications informed the selection of acceptance criteria.

THINQ's segmentation accuracy of brain structures compared to ground-truth segmentations of 3D T1 MRI scans was evaluated using the Dice similarity coefficient metric. Accuracy of Intracranial Volume (ICV) was evaluated using the Absolute Percent Difference (APD) metric. Table 1 lists the results, including the Absolute Volume Error (AVE) and Relative Volume Error (RVE) metrics.

Structure	Accuracy Metric	Mean (StDev)
Whole Brain	Dice	0.94 (0.01)
	AVE (cm^3)	327.00 (111.48)
	RVE	0.30 (0.13)
Total Gray Matter	Dice	0.82 (0.02)
	AVE (cm^3)	174.63 (46.42)
	RVE	0.24 (0.05)
Total White Matter	Dice	0.87 (0.04)
	AVE (cm^3)	65.67 (37.38)
	RVE	0.18 (0.12)
Left Cortical Gray Matter	Dice	0.92 (0.06)
	AVE (cm^3)	10.59 (6.51)
	RVE	0.05 (0.03)
Right Cortical Gray Matter	Dice	0.92 (0.07)
	AVE (cm^3)	10.43 (6.67)
	RVE	0.05 (0.03)
Left Frontal Lobe	Dice	0.90 (0.06)
	AVE (cm^3)	5.44 (3.83)
	RVE	0.07 (0.05)
Right Frontal Lobe	Dice	0.90 (0.06)
	AVE (cm^3)	5.07 (3.86)
	RVE	0.06 (0.05)
Left Parietal Lobe	Dice	0.88 (0.08)
	AVE (cm^3)	4.06 (3.04)
	RVE	0.08 (0.06)
Right Parietal Lobe	Dice	0.88 (0.08)
	AVE (cm^3)	3.85 (2.86)
	RVE	0.07 (0.06)
Left Occipital Lobe	Dice	0.82 (0.07)
	AVE (cm^3)	1.57 (1.22)
	RVE	0.07 (0.05)
Right Occipital Lobe	Dice	0.82 (0.08)
	AVE (cm^3)	1.92 (1.97)
	RVE	0.08 (0.09)
Left Temporal Lobe	Dice	0.89 (0.06)
	AVE (cm^3)	2.08 (1.89)
	RVE	0.04 (0.04)
Right Temporal Lobe	Dice	0.89 (0.06)

	AVE (cm^3)	2.11 (1.81)
	RVE	0.04 (0.04)
Left Cerebral White Matter	Dice	0.86 (0.04)
	AVE (cm^3)	32.60 (18.80)
	RVE	0.18 (0.12)
Right Cerebral White Matter	Dice	0.86 (0.04)
	AVE (cm^3)	33.07 (18.88)
	RVE	0.18 (0.12)
Left Lateral Ventricle	Dice	0.86 (0.07)
	AVE (cm^3)	2.32 (1.69)
	RVE	0.17 (0.15)
Right Lateral Ventricle	Dice	0.85 (0.07)
	AVE (cm^3)	2.19 (1.59)
	RVE	0.18 (0.14)
Left Hippocampus	Dice	0.78 (0.03)
	AVE (cm^3)	0.45 (0.29)
	RVE	0.14 (0.09)
Right Hippocampus	Dice	0.79 (0.03)
	AVE (cm^3)	0.39 (0.28)
	RVE	0.12 (0.10)
Left Amygdala	Dice	0.66 (0.05)
	AVE (cm^3)	0.60 (0.17)
	RVE	0.68 (0.24)
Right Amygdala	Dice	0.64 (0.06)
	AVE (cm^3)	0.69 (0.19)
	RVE	0.74 (0.27)
Left Caudate	Dice	0.78 (0.07)
	AVE (cm^3)	0.50 (0.35)
	RVE	0.17 (0.14)
Right Caudate	Dice	0.78 (0.07)
	AVE (cm^3)	0.53 (0.34)
	RVE	0.18 (0.13)
Left Putamen	Dice	0.82 (0.04)
	AVE (cm^3)	0.83 (0.35)
	RVE	0.20 (0.10)
Right Putamen	Dice	0.82 (0.03)
	AVE (cm^3)	0.89 (0.35)
	RVE	0.21 (0.08)
Left Thalamus	Dice	0.82 (0.03)
	AVE (cm^3)	1.51 (0.53)
	RVE	0.19 (0.05)
Right Thalamus	Dice	0.83 (0.03)
	AVE (cm^3)	1.38 (0.45)
	RVE	0.18 (0.04)
Left Cerebellum	Dice	0.91 (0.02)
	AVE (cm^3)	2.10 (1.43)

	RVE	0.03 (0.02)
Right Cerebellum	Dice	0.92 (0.02)
	AVE (cm^3)	2.07 (1.49)
	RVE	0.03 (0.02)
Intracranial Volume ICV	APD	3.42 (2.05)
	AVE (cm^3)	50.18 (31.92)
	RVE	0.03 (0.02)

Table 1: Accuracy testing results

Reproducibility of brain structure segmentation of repeated 3D T1 MRI scans for same-subjects was evaluated by using the Absolute Percent Difference (APD) metric, shown in Table 2.

Structure	**Reproducibility APD Mean (StDev)**
Whole Brain	0.34 (0.29)
Total Gray Matter	0.83 (0.80)
Total White Matter	1.04 (1.12)
Left Cortical Gray Matter	1.08 (0.89)
Right Cortical Gray Matter	1.04 (0.88)
Left Frontal Lobe	1.31 (1.30)
Right Frontal Lobe	1.57 (2.41)
Left Parietal Lobe	1.50 (1.31)
Right Parietal Lobe	1.67 (2.73)
Left Occipital Lobe	1.49 (1.16)
Right Occipital Lobe	2.00 (1.41)
Left Temporal Lobe	1.24 (1.37)
Right Temporal Lobe	1.39 (1.15)
Left Cerebral White Matter	1.15 (1.09)
Right Cerebral White Matter	1.10 (1.20)
Left Lateral Ventricle	1.44 (1.21)
Right Lateral Ventricle	1.55 (1.12)
Left Hippocampus	1.56 (1.76)
Right Hippocampus	1.49 (1.57)
Left Amygdala	1.25 (1.23)
Right Amygdala	1.72 (1.36)
Left Caudate	1.14 (1.22)
Right Caudate	1.24 (1.10)
Left Putamen	1.41 (1.15)
Right Putamen	1.29 (0.90)
Left Thalamus	0.86 (0.59)
Right Thalamus	0.75 (0.63)
Left Cerebellum	0.62 (0.58)
Right Cerebellum	0.60 (0.54)
Intracranial Volume ICV	0.30 (0.29)

Table 2: Reproducibility testing results

THINQ performs a quantitative imaging function. The validation of THINQ addressed typical sources of error in quantitative imaging values by including in its image testing dataset a wide range of patient characteristics (e.g. age, gender, disease case) and image acquisition varieties (e.g. scanner manufacturer, image acquisition protocols, data noise and artifacts). The validation dataset was composed of 645 unique MR images.

8 Conclusion

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, THINQ™ is substantially equivalent to its predicate device, and its technological differences do not raise questions of safety and effectiveness.