December 13, 2019

Qynapse
% Mr. Michael Daniel
President
Daniel & Daniel Consulting, LLC
340 Jones Lane
GARDNERVILLE NV 89460

Re: K192531
Trade/Device Name: QyScore Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 29, 2019
Received: December 2, 2019

Dear Mr. Daniel:

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,

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)*
K192531

Device Name
Qyscore Software

Indications for Use *(Describe)*
QyScore 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. QyScore is not intended for use in clinical scenarios that require evaluation of the number of the white matter hyperintensities.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K192531

Applicant Information:

Date Prepared:	December 4, 2019
Name:	Qynapse Address: 67 rue Saint Jacques 75005 Paris, France
Contact Person:	Michael A Daniel, Consultant madaniel@clinregconsult.com
Mobile Number:	(415) 407-0223
Office Number:	(775) 392-2970
Facsimile Number:	(610) 545-0799

Device Information:

Trade Name:	QyScore Software
Common Names:	Medical Image Processing Software
Classification Name(s):	Picture archiving and communications system
Product Code/ Regulation:	LLZ/21 CFR 892.2050
Classification:	Class II

Predicate Device:

- NeuroQuant Medical Image Processing Software – K170981

Device Description:

QyScore automatically provides segmentations and measures of brain structures and lesions from a set of MR images for patients between the ages of 20 and 90.

The software retrieves DICOM MRI data (3DT1 and T2FLAIR series) from a DICOM server and sends it to an analysis server for automatic segmentation of grey matter, white matter, hippocampus, amygdala and white matter hyperintensities. The outputs of the software include an electronic report and color overlays of the segmentation on the input images.

The results are displayed in a dedicated graphical user interface, allowing the user to:

- Browse the segmentations and the measures,
- Compare the results of segmented brain structures to a reference healthy population,
- Read and edit a PDF report.

QyScore integrates with leading RIS/PACS systems and can be operated with any MRI scan from 1.5T and 3T scanners for T1 MRI processing, and 3T scanners for T2FLAIR MRI processing.

Indications for Use:

QyScore 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. QyScore is not intended for use in clinical scenarios that require evaluation of the number of the white matter hyperintensities.

Summary Comparison to Predicate:

	Subject device	**Predicate device**
	QyScore v1.7.0	**NeuroQuant v2.2**
510(k) number	N/A	K170981
Regulation number	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	QyScore 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. QyScore is not intended for use in clinical scenarios that require evaluation of the number of the white matter hyperintensities.	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 and lesions - Automatic segmentation and quantification of brain structures using a dynamic 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

	- Results displayed through graphical user interface	
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
Processing architecture	Automated internal pipeline that performs: - bias correction - segmentation - lesions quantification - volume calculation - report generation	Automated internal pipeline that performs: - bias correction - segmentation - lesions quantification - volume calculation - report generation
Data Source	MRI scanner: 3DT1 and FLAIR MRI scans acquired with specified protocols. Supports DICOM format as input.	MRI scanner: 3DT1 and FLAIR MRI scans acquired with specified protocols. 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 function: scan protocol verification 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

QyScore and the predicate device are software for automatically identifying and quantifying the volumes of brain structures, automatic labeling and visualization. The devices have the

same intended use and operating principle. They take MR brain images as input and generate an electronic report with similar quantitative information. For both devices, output volumes are compared to a normative dataset of control subjects computed based on MRI data from normal control subjects.

QyScore and NeuroQuant achieve their intended use based on a similar principle, since the quantification system relies on skull stripping (brain extraction), a brain segmentation based on a probabilistic atlas and image intensity information, and volume calculations of the segmented brain structures. Both devices normalize the volumes with the intracranial volume to allow for the statistical comparison with a normative dataset.

Both devices are DICOM compatible and operate on off-the-shelf hardware. QyScore is used by medical personnel or neuroimaging trained personnel. NeuroQuant is used by physicians skilled in brain MR imaging.

Summary of Performance Testing
Testing performed on the QyScore software included:

- Software verification testing
- Software validation testing
- Human factors testing
- Validation studies based on scientific literature
- Evaluation of segmentation accuracy

For the accuracy evaluation, QyScore segmentations were compared to expert manual segmentations for each segmented structure. Several acceptance criteria have been set in agreement with the literature, on both overlap metrics and volume difference metrics.

The Dice coefficients exceed 85% on whole brain regions and are in the range of 75%-85% for subcortical brain structures segmented from 3DT1 MRI scans. The lesions segmentation, performed on (3DT1+T2FLAIR) paired sequences, was assessed on a broad validation population, with lesion loads ranging from 0.09mL to 87.65mL. The resulting mean absolute volume difference is 3.34mL.

The performance testing demonstrated that the software meets its intended use, product specifications and user needs.

Software

Qynapse followed IEC 62304 and the FDA Guidance Document, “General Principles of Software Validation; Final Guidance for Industry and FDA Staff” (January, 2002) with respect to software development and validation. The QyScore software is classified as a “moderate level of concern” per the FDA guidance document.

Verification and validation testing was completed in compliance with the following standards and guidance documents:

- ISO 14971:2012, Medical devices – application of risk management to medical devices
- AAMI ANSI IEC 62304:2006, Medical device software – Software life cycle processes

- General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (January, 2002)
- AAMI ANSI IEC 62366:2007, Medical devices – Application of usability engineering to medical devices

Testing described in this 510(k) consists of verification of all design input requirements and product specifications. All clinical input requirements were validated.

Conclusion

Based upon the intended use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the QyScore software has been shown to be substantially equivalent to the legally marketed predicate device. The technological differences do not raise any new questions of safety and effectiveness.