December 13, 2023

Quibim S.L.
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells US LLP
555 13th St. NW
Washington, DC 20005

Re: K232231
Trade/Device Name: QP-Brain®
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: November 15, 2023
Received: November 15, 2023

Dear John Smith:

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)*
K232231

Device Name

QP-Brain®

Indications for Use *(Describe)*

QP-Brain® is a medical imaging processing application intended for automatic labeling and volumetric quantification of segmentable brain structures and white matter hyperintensities (WMH) from a set of adults and adolescents 18 and older MR images. Volumetric measurements may be compared to reference percentile data. The application is used by clinicians with proper training, as a support tool in assessment of structural MRIs. Patient management decisions should not be based solely on the results of the device.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

510(k) SUMMARY
Quibim's QP-Brain®

Submitter
Quibim S.L.
Avenida Aragon 30, 13th floor, Office I-J, 46021 Valencia (Spain)

Phone:
- +34 961 243 255

Contact Person:
- Ángel Alberich Bayarri, CEO and Founder of Quibim (angel@quibim.com)
- Josep Hortigüela Zamora, VP of Quality Assurance and Regulatory Affairs (josephortiguela@quibim.com)

Date Prepared:
November 15, 2023

Name of Device: QP-Brain®
Common or Usual Name: Medical image management and processing system
Classification Name: 892.2050 Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ

Predicate Device
- Manufacturer's name: CorTechs Labs, Inc. 4690 Executive Drive, Suite 250, San Diego, CA 92121
- Device's trade name: NeuroQuant
- 510(k) number: K170981
- Product code: LLZ

Reference Devices
Reference Device #1:
- Manufacturer's name: Quantib B.V. Westblaak 106, 3012 KM Rotterdam (Netherlands).
- Device's trade name: Quantib™ Brain 1.3
- 510(k) number: K173939
- Product code: LLZ

Reference Device #2:
- Manufacturer's name: Qynapse. PariSanté Campus, 2-10 rue d'Oradour-sur-Glane, 75015 Paris, France
- Device's trade name: Qyscore Software
- 510(k) number: K192531
- Product code: LLZ

Device Description

QP-Brain® is a medical image processing and analyzing software intended for image processing to analyze brain MR imaging studies. These brain MR images, when interpreted by clinicians with proper training, may yield clinically useful information.

QP-Brain® is an automated MR imaging post-processing medical device software that uses 3D T1-weighted (T1w) Gradient Echo structural MRI scans to provide a quantitative imaging analysis and automatic segmentation of brain regions. If T2 FLAIR images are uploaded, QP-Brain® uses this sequence to automatically identify white matter hyperintensities using Artificial Intelligence.

Once the T1 MR or T2 FLAIR has been uploaded, QP-Brain® will check the available sequences for compatibility before automatically launching the analysis.

The output of the medical device consists of specific volumes with segmentation overlay as well as different reports with quantitative information. The outputs can be returned to and displayed on third-party DICOM workstations and Picture Archive and Communication Systems (PACS).

In case age and gender information is available on the study DICOM tags for brain structure analysis module, all quantified volumes are framed in a normative database to be compared with cognitively normal adults of the same age and gender.

QP-Brain® also allows for longitudinal information reporting if a patient has acquired more than one MRI over time.

Intended Use / Indications for Use

QP-Brain® is a medical imaging processing application intended for automatic labeling and volumetric quantification of segmentable brain structures and white matter hyperintensities (WMH) from a set of adults and adolescents 18 and older MR images. Volumetric measurements may be compared to reference percentile data. The application is used by clinicians with proper training, as a support tool in assessment of structural MRIs. Patient management decisions should not be based solely on the results of the device.

Comparison to predicate device

The QP-Brain® and predicate devices differs on the following elements:

- QP-Brain® and the predicate device NeuroQuant® have very similar indications statements. Both are intended for a medical image processing application intended for automatic labeling and volumetric quantification of segmentable brain structures and white matter hyperintensities (WMH) from a set of MR images. NeuroQuant® uses the word “lesions” meaning White Matter Hyperintensities points to hyperintense area, which is within QP-Brain® scope. This wording difference does not alter the intended use effect of QP-Brain® as a support tool to clinicians in assessment of structural MRIs.

- QP-Brain® has the same intended use environment and intended user, and the intended patient population (adult patients and adolescent patients aged 18 through 21) is covered by the intended patient population of the predicate device (pediatric and adult patients).

Summary of Technological Characteristics

At a high level, the subject and predicate devices are based on the following same technological elements:

- Both devices are compatible with DICOM standard.
- Both devices have the same input to run the analysis module: 3D T1 MRI scans (for brain structures) and T2 FLAIR M (for White Matter Hyperintensities) acquired with specified protocols.
- Both devices have the same automated internal pipeline to perform the analysis.
- Both devices have the same clinical outputs.

The following technological differences exist between the subject and predicate devices:

- The difference in processing architecture (since they are not exactly the same algorithm), could affect its safety or effectiveness, but does not raise any different questions of safety or effectiveness, because a set of verification and validation tests (performance testing) demonstrate the safety and effectiveness of QP-Brain®.

A table comparing the key features of the subject and predicate devices is provided below:

Table 1: Comparison of key features of QP-Brain® (Quibim) and the predicate device NeuroQuant® (CorTechs Labs, Inc.)

Feature	**Proposed device: QP-Brain® (K232231)**	**Predicate device: NeuroQuant® (K170981)**
REGULATORY DATA		
Class	II	II
Regulation name	Picture Archiving and Communication System	Medical Image management and processing system
Regulation number	21 CFR 892.2050	21 CFR 892.2050
Classification Panel	Radiology	Radiology
Product Code	QIH, LLZ	LLZ
Manufacturer:	Quibim S.L.	CorTechs Labs, Inc.
INTENDED USE		
Medical device description	QP-Brain® is a medical imaging processing application intended for automatic labeling and volumetric quantification of	NeuroQuant® is intended for automatic labeling, visualization and volumetric quantification of segmentable brain

Feature	Proposed device: QP-Brain® (K232231)	Predicate device: NeuroQuant® (K170981)
	segmentable brain structures and white matter hyperintensities (WMH) from a set of adults and adolescents 18 and older MR images.	structures and lesions 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.
Medical device intended use environment	Software as a Medical Device, DICOM compatible and operate on off-the-self hardware (multiple vendors).	Software as a Medical Device, DICOM compatible and operate on off-the-self hardware (multiple vendors).
Medical device intended user	The application should be used by clinicians with proper training, as a support tool in assessment of structural MRIs. Patient management decisions should not be based solely on the results of the device.	NeuroQuant® is 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.
Medical device intended patient population	Adult patients and adolescent patients aged 18 through 21 with brain MRI study. Available up to 94 years.	Adult and pediatric patients with brain MRI study. Available for ages 3 to 100 years.
CHARACTERISTICS		
Clinical 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. - 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.
Data source	MRI scanner: 3D T1 MRI scans (for brain structures)	MRI scanner: 3D T1 MRI scans (for brain volumetry)

Feature	Proposed device: QP-Brain® (K232231)	Predicate device: NeuroQuant® (K170981)
	and T2 FLAIR MR (for White Matter Hyperintensities) acquired with specified protocols. QP-Brain® supports DICOM format as input.	and T2 FLAIR MR (for White Matter Hyperintensities) acquired with specified protocols. NeuroQuant® supports DICOM format as input.
Processing architecture	Automated internal pipeline that performs: - artifact correction - segmentation - atlas-based parcellation - WMH quantification - volume calculation - report generation	Automated internal pipeline that performs: - artifact correction - segmentation - atlas-based parcellation - lesion quantification - volume calculation - report generation
Safety	Automated quality control function: scan protocol verification. Results must be reviewed by a clinician with proper training.	Automated quality control functions: - Tissue contrast check. - Scan protocol verification. - Atlas alignment check. Results must be reviewed by a trained physician.

Performance Data

QP-Brain® software was developed according to FDA recognized consensus standards for software development. Software verification and validation was performed following V&V plans and protocols verifying that product specifications were met.

For the performance evaluation, QP-Brain® outputs were compared to manual expert segmentation (reference standard) for Gray Matter (GM), White Matter (WM), Cerebrospinal fluid (CSF) and White Matter Hyperintensities (WMH).

For brain regions segmented from 3D T1 MRI scans, the results between manual segmentation and QP-Brain® segmentation are summarized below:

Table 2: Summary of the performance testing for QP-Brain® Brain volumetry analysis module.

Region	DICE Score	Relative Volume Difference
GM	0.983 (0.981 – 0.986)	2.846 (2.523 – 3.008)
WM	0.990 (0.988 – 0992)	1.643 (0.923 – 1.684)
CSF	0.955 (0944 – 0.965)	7.495 (3.950 – 7.7.18)
ICV	0.994 (0.994 – 0.995)	0.496 (0.298 – 0.694)

For White Matter Hyperintensities segmented from T2 FLAIR, the results between manual segmentation and QP-Brain® segmentation are summarized below:

Table 3: Summary of the performance testing for QP-Brain® Brain WMH analysis module.

Size	DICE Score	Absolute volume error	F1 score
Low WMH	0.506	0.675 mL	0.692
Medium WMH	0.636	2.544 mL	
High WMH	0.774	3.097 mL	
Very High WMH	0.885	7.833 mL	

Wilcoxon signed-rank test is used to establish uncertainty intervals. The results are summarized below:

Table 4: Summary of the performance testing for QP-Brain® Brain WMH analysis module (confidence intervals).

Size	DICE Score	Absolute volume error	F1 score
Low WMH	0.406 (0.360 – 0.450)	0.455 mL (0.317 – 0.682)	0.701 (0.666 – 0.739)
Medium WMH	0.622 (0.559 – 0.699)	2.084 mL (1.190 – 3.704)	
High WMH	0.748 (0.707 – 0.790)	2.871 mL (1.311 – 4.763)	
Very High WMH	0.806 (0.677 – 0.923)	5.668 mL (2.853 – 15.831)	

The Pearson's correlation coefficient result for the WMH count is 0.88.

The test results demonstrate that QP-Brain® functioned as intended, is acceptable for clinical use, and is as safe and effective as its predicate device, without introducing new questions of safety and efficacy.

Conclusions

The QP-Brain® is as safe and effective as the NeuroQuant®. The QP-Brain® has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended diagnostic use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the QP-Brain® and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the QP-Brain® is as safe and effective as the NeuroQuant®. Thus, the QP-Brain® is substantially equivalent.