Quantib B.V.   March 9, 2018
℅ Floor van Leeuwen
Quality & Regulatory Manager
Westblaak 106
3012 KM   Rotterdam
NETHERLANDS

Re: K173939
     Trade/Device Name: Quantib™ Brain 1.3
     Regulation Number: 21 CFR 892.2050
     Regulation Name: Picture archiving and communications system
     Regulatory Class: Class II
     Product Code: LLZ
     Dated: December 22, 2017
     Received: December 26, 2017

Dear Floor van Leeuwen:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

Indications for Use

510(k) Number *(if known)*
K173939

Device Name
Quantib™ Brain 1.3

Indications for Use *(Describe)*

Quantib™ Brain is a non-invasive medical imaging processing application that is intended for automatic labeling, visualization, and volumetric quantification of segmentable brain structures from a set of magnetic resonance (MR) images. The Quantib™ Brain output consists of segmentations, visualizations and volumetric measurements of grey matter (GM), white matter (WM), and cerebrospinal fluid (CSF). The output also visualizes and quantifies white matter hyperintensity (WMH) candidates. Users need to review and if necessary, edit WMH candidates using the provided tools, before validation of the WMHs. It is intended to provide the trained medical professional with complementary information for the evaluation and assessment of MR brain images and to aid the trained medical professional in quantitative reporting. Quantib™ Brain is a post-processing plugin for the GE Advantage Workstation (AW 4.7) or AW Server (AWS 3.2) platforms.

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.

Quantib™ Brain 1.3 510(k) Summary

1 SUBMITTER

Quantib B.V.

Westblaak 106

3012 KM Rotterdam

Phone: (+31) 108 41 17 49

Contact Person: Floor van Leeuwen

Date Prepared: December 20, 2017

2 DEVICE

Name of Device: Quantib™ Brain 1.3

Common or Usual Name: Quantib™ Brain

Classification Name: System, image processing, radiology (892.2050)

Regulatory Class: II

Product Code: Picture archiving and communication system (LLZ)

3 PREDICATE DEVICE

Device: Quantib™ Brain 1.2

Manufacturer: Quantib BV

510(k) Reg. No: K163013

This predicate has not been subject to a design-related recall

Regulatory Class: II

Product Code: Picture archiving and communication system (LLZ)

4 DEVICE DESCRIPTION

Quantib™ Brain is post-processing analysis software for the GE Advantage Workstation (AW 4.7) and AW Server (AWS 3.2) platforms using Volume Viewer Apps. 13.0 Ext 4 (or higher). It is intended for automatic labeling, visualization, and volumetric quantification of identifiable brain structures from magnetic resonance images (a 3D T1-weighted MR image, with an additional T2-weighted FLAIR MR image for white matter hyperintensities (WMH) segmentation). The segmentation system relies on a number of atlases each consisting of a 3D T1-weighted MR image and a label map dividing the MR image into different tissue segments. Quantib™ Brain provides quantitative information on both the absolute and relative volume of the segmented regions. The automatic WMH segmentation is to be reviewed and if necessary, edited by the user before validation of the segmentation, after which volumetric information is accessible.

Longitudinal analysis can be performed for the brain tissue segmentation and WMH segmentation in order to compare multiple exams of an individual patient. Quantib Brain is intended to provide the trained medical professional with complementary information for the evaluation and assessment of MR brain images and to aid the radiology specialist in quantitative reporting.

5 INDICATIONS FOR USE

Indications for use Quantib™ Brain 1.3
Quantib™ Brain is a non-invasive medical imaging processing application that is intended for automatic labeling, visualization, and volumetric quantification of segmentable brain structures from a set of magnetic resonance (MR) images. The Quantib™ Brain output consists of segmentations, visualizations and volumetric measurements of grey matter (GM), white matter (WM), and cerebrospinal fluid (CSF). The output also visualizes and quantifies white matter hyperintensity (WMH) candidates. Users need to review and if necessary, edit WMH candidates using the provided tools, before validation of the WMHs. It is intended to provide the trained medical professional with complementary information for the evaluation and assessment of MR brain images and to aid the trained medical professional in quantitative reporting. Quantib™ Brain is a post-processing plugin for the GE Advantage Workstation (AW 4.7) or AW Server (AWS 3.2) platforms.

Indications for use comparison with predicate device
The intended use of the modified device is **equal** to the intended use of the previously cleared predicate device [K163013].

6 DEVICE MODIFICATIONS

Quantib™ Brain 1.3 is an update of Quantib™ Brain 1.2 (the predicate device). The differences are the following:

6.1 BRAIN VOLUMETRY ALGORITHM
To improve the ICV results, a different voting mechanism is applied.

6.2 WHITE MATTER HYPERINTENSITIES ALGORITHM
In the White Matter Hyperintensities segmentation algorithm of Quantib Brain 1.3 we have implemented a different type of classifier to classify the set of candidate lesions. To improve the algorithm performance, we have extended the set of features used in the classifier.

6.3 LONGITUDINAL REVIEW ALGORITHM
No changes are made to the longitudinal review algorithm.

7   TECHNOLOGICAL CHARACTERISTICS

The following technological characteristics are the same for Quantib™ Brain 1.3 and its predicate device Quantib Brain 1.2:

- Intended use and Indications for use
- Target users, anatomical site and usage location
- Design
- Compatibility with the environment and other devices

The following technological characteristics are different:

- Performance: Assessment of the performance of the new WMH algorithm is added. The dataset used for validation has been extended with additional patient data.
- Reported measures: When a contrast-enhanced 3DT1w scan (in combination with a T2w FLAIR scan) are used as input data, the absolute and relative cross sectional volumes of the brain tissues, and therefore also the relative WMH volumes, are not reported. Absolute WMH measures and WMH longitudinal analysis are displayed.
- Required input: Contrast-enhanced 3DT1w scans are no longer excluded from processing of WMH. However, not all measures are reported to the user whenever a contrast-enhanced scan is used as input

8   PERFORMANCE DATA:

1.   Quality and safety
Quantib™ Brain 1.3 was designed in compliance with the following process standards:

- IS0 14971 – Medical devices - Application of risk management to medical devices
- IEC 62304 – Medical device software – Software life cycle processes

The following quality assurance measures were applied to Quantib™ Brain 1.3 development:

- Risk and hazard analysis
- Design reviews
- Unit level testing
- Integration testing
- System testing
- Performance testing
- Usability engineering

2. Algorithm performance
To validate the quality of Quantib™ Brain volume measurements and segmentations, the relative volumes and the segmentations were compared to relative volumes derived from manual segmentations and to manual segmentations of the same scan. This analysis was performed for GM, WM, CSF, ICV, and WMHs.

For Brain Volumetry (segmentation and measures of GM, WM, CSF, and ICV) the test set included 33 3DT1w MR images. The set was carefully selected to include data from multiple vendors and a series of representative scan settings. For each scan we selected six (6) slices for comparison. The results are summarized below.

	Dice index	Absolute difference of the relative volumes [pp]
CSF	0.78 ± 0.05	1.8 ± 1.0
GM	0.84 ± 0.02	2.7 ± 2.0
WM	0.86 ± 0.02	2.8 ± 1.9
ICV	0.97 ± 0.00	

Results of comparison between manual and automatic brain tissue segmentation. Reported values are averages ± std. dev., computed over 6 segmented slices of 33 scans. The Dice index provides a measure for overlap of manual and automatic segmentations (1 = perfect overlap). The absolute differences of the relative volumes (of the brain tissues) are averages ± std. dev. in percentage points.

The test set for the White Matter Hyperintensities protocol included 45 3DT1w images, of which 7 contrast-enhanced, all with corresponding T2w FLAIR images. This set also represented various scan settings. WMHs were manually segmented on the T2w FLAIR images and compared to Quantib™ Brain automatic segmentation output. The average Dice overlap between the manual segmentations and Quantib™ Brain segmentations was 0.61 ± 0.13 (over all cases). The absolute difference of the relative volumes (for WMHs) was 0.5 ± 0.5 percentage points (over 38 cases without contrast-enhancement).

9   CONCLUSIONS

By virtue of its intended use and physical and technological characteristics, Quantib™ Brain 1.3 is substantially equivalent to a device that has been approved for marketing in the United States. The performance data shows that Quantib™ Brain 1.3 is as safe and effective as the predicate device.