DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 6, 2017

Quantib B.V.
% Mr. Rudolf Scholte
CEO
Westblaak 106
Rotterdam, Zuid-Holland 3012KM
NETHERLANDS

Re: K163013
Trade/Device Name: Quantib™ Brain 1.2
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 13, 2016
Received: December 14, 2016

Dear Mr. Scholte:

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 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 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 yours,

For

Robert 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)*
K163013

Device Name
Quantib™ Brain 1.2

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.

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510(k) Summary

I. SUBMITTER

Quantib B.V.
Westblaak 106
3012 KM Rotterdam
Phone: (+31) 108 41 17 49
Contact Person: Rudolf Scholte
Date Prepared: October 27th, 2016

II. DEVICE

Name of Device: Quantib™ Brain 1.2
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)

III. PREDICATE DEVICE

Device: Quantib™ Brain 1
Manufacturer: Quantib B.V.
510(k) Reg. No: K153351
This predicate has not been subject to a design-related recall.
Regulatory Class: II
Product Code: Picture archiving and communication system (LLZ)

IV. 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. 12.3 Ext 8 (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.

V. INTENDED USE

Intended use Quantib™ Brain 1.2

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.

Intended use predicate device

The intended use of the modified device is **equal** to the intended use of the previously cleared predicate device [K153351].

VI. DEVICE MODIFICATIONS

Quantib™ Brain 1.2 is an update of Quantib™ Brain 1 (the predicate device). The differences are the following:

1. User interface modifications of the White Matter Hyperintensities cross sectional analysis.

In the predicate device, each segmented white matter hyperintensity was listed as a separate item in the on-screen table containing all measurements. In case of many hyperintensities (e.g. more than 20), this table becomes over-populated. The software was changed to only display one measurement which contains the sum of all hyperintensities. Individual volumes can still be assessed in the viewers. There is no impact of this change on the final report. The report shows in both the predicate and modified device the total white matter hyperintensity volume and the burden (number of hyperintensities).

2. Two additional review steps to facilitate longitudinal comparison of Brain Volumetry and White Matter Hyperintensities.

This modification facilitates the comparison of Quantib Brain analyses for MRI studies of multiple time points of the same patient. Two or more time points can be loaded and all cross sectional measurements will be linked in the on-screen measurement table and presented as differences using mathematical subtraction. The viewers allow for side-by-side visualization of the MRI scans and the segmentations. The final report is extended by adding the measurement differences between time points and the number of appearing and disappearing hyperintensities. This modification did not require changes in the underlying automated segmentation algorithms and all extra information is derived from the cross sectional measurements. To help the user in distinguishing between consistent, new and

disappearing WMH, a straight forward algorithm based on overlapping voxels was added to the software for which the performance was assessed.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Based on these two modifications, the following technological characteristics are the same:

- Intended use and Indications for use
- Target users, anatomical site and usage location
- Design
- Compatibility with the environment and other devices
- Performance of core segmentation (brain volumetry and WMH) algorithms
- Reported measures of cross sectional brain volumetry and WMH analysis
- Required input for cross sectional analysis

The following technological characteristics are different:

- Performance: Assessment of the performance of the newly added WMH longitudinal labeling algorithm was added.
- Reported measures: New measures related to longitudinal comparison were added. These measures are directly derived from already existing cross sectional metrics using mathematical subtraction.
- Required input: More than one exam of the same patient (longitudinal data) can now be used.

VIII. PERFORMANCE DATA

1. Quality and safety

Quantib™ Brain 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
- IEC 62366 – Medical devices - Application of usability engineering to medical devices

The following verification and validation reviews and tests are performed:

- Requirements review
- Architectural review
- Unit tests
- Functional tests
- Story verification
- Code analysis
- Code review
- System tests
- Integration tests
- Regression tests

- Algorithm tests
- Tool validation
- SOUP analysis

The changes made in Quantib™ Brain 1.2 do not affect the safety of the device. This conclusion is based on:

- Failure mode and effects analysis on the added functionality.
- Risk category classification of new software components.

2. Algorithm performance

To help the user in distinguishing between consistent, new and disappearing WMH, a straight forward algorithm based on overlapping voxels was added to the software for which the performance was assessed. This algorithm was validated on 12 datasets of different subjects, each consisting of a baseline exam and 1 to 3 follow-up exams. WMHs were labeled as consistent, new and disappearing in a comparison of follow-up exams to their preceding exam. The automatic labeling of WMHs was for 99.6% of the WMH volume identical to manual labeling of these WMHs.

The performance of the already existing algorithms did not change.

VIIII. CONCLUSIONS

By virtue of its intended use and physical and technological characteristics, Quantib™ Brain 1.2 is substantially equivalent to a device that has been approved for marketing in the United States. The performance data shows that Quantib™ Brain 1.2 is as safe and effective as the predicate device.