



September 25, 2025

Quantib BV
Nathan Hunt
Head of Quality, Regulatory, and Compliance
Westblaak 130
Rotterdam, Zuid-Holland 3012 KM
Netherlands

Re: K251527
Trade/Device Name: Brain WMH
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: August 19, 2025
Received: August 19, 2025

Dear Nathan Hunt:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,

A handwritten signature in black ink, appearing to read 'D. Krainak', is written over a faint, light blue background watermark of the FDA logo.

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
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

Indications for Use

510(k) Number (if known)

K251527

Device Name

Brain WMH

Indications for Use (Describe)

Intended Use

Brain WMH is intended for automatic labeling, visualization, and volumetric quantification of WMH from T2w FLAIR MR images. The output consists of segmentations, visualizations and volumetric measurements of WMH. 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.

Intended User Population

The intended users of Brain WMH are trained medical professionals.

Intended Patient Population

Brain WMH is intended for post-processing of brain magnetic resonance imaging (MRI) data from patients 22 years of age or older, without pathologies (e.g. tumor or stroke), and treatment induced features (e.g. from prior surgery or radiation treatment), and without contrast enhancement.

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.

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510(k) Summary
Quantib BV
Brain WMH

In accordance with 21 CFR 807.92 the following summary of information is provided, on this date, September 10th, 2025:

1. 510(k) Submitter

Quantib BV
Westblaak 130
3012 KM Rotterdam
Tel: +31 10 841 1749

Contact Person:

B. Nathan Hunt
Head of Quality, Regulatory, and Compliance
Email: regulatory@deephealth.com

Date prepared:

September 10th, 2025

2. Device

Trade Name of Device:

Brain WMH

Common or Usual Name:

Medical Image Software

Classification Names:

Medical image management and processing system (892.2050)

Regulation Class: II

Product Code: QIH

3. Predicate Device

Trade Name of Device:

Quantib ND (K213737)

Common or Usual Name:

Medical Image Software

Classification Names:

Medical image management and processing system (892.2050)

Regulation Class: II

Product Code: LLZ

4. Device Description

Brain WMH is a software as a medical device (SaMD) that provides automatic quantification of white matter hyperintensities (WMHs) based on magnetic resonance (MR) images to assist trained medical professionals. The device takes fluid-attenuated inversion recovery (FLAIR) MR images as input. Its output consists of a report in DICOM encapsulated pdf and DICOM secondary capture format, and DICOM secondary captures of the segmentations as color overlay on the input image.

5. Indications for Use

Brain WMH is intended for automatic labeling, visualization, and volumetric quantification of WMH from T2w FLAIR MR images. The output consists of segmentations, visualizations and volumetric measurements of WMH. 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.

Intended User Population

The intended users of Brain WMH are trained medical professionals.

Intended Patient Population

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6. Predicate Device Comparison

The subject device and the predicate device are both Class II medical devices regulated under 21 CFR 892.2050. As main functionality, the devices provide segmentation and quantification of WMHs and support longitudinal analysis. Furthermore, the devices have similar indications for use, identical intended users, and target the same anatomical site.

There are minor technical differences between the subject device and the predicate device:

Brain WMH employs an updated artificial intelligence-based algorithm for WMH segmentation, whereas the predicate device uses a different machine learning approach. Both methodologies are functionally similar in purpose and provide segmentation capabilities. Both devices undergo validation using comparable performance metrics and evaluation processes.

Brain WMH requires only T₂ FLAIR imaging as input, while the predicate device requires both FLAIR and T₁ scans. This streamlined input requirement enhances clinical workflow efficiency by reducing imaging requirements while improving segmentation performance.

Brain WMH operates as a fully automatic system, whereas the predicate device includes manual adjustment functionality. This fully automatic approach streamlines clinical workflow while maintaining the same core WMH segmentation and quantification function. Both devices are intended for use by trained medical professionals who review and interpret results within established clinical workflows.



Brain WMH segments WMHs and labels them according to their anatomical location, while the predicate performs segmentation of WMHs without anatomical location labeling.

Brain WMH provides specialized WMH segmentation and quantification, while the predicate device offers both brain structure segmentation and WMH analysis. This focused approach allows Brain WMH to deliver a specialized WMH assessment.

Despite these technical differences, both devices maintain equivalent core functionality for WMH segmentation and volumetric quantification. The technical modifications represent improvements in workflow efficiency and algorithmic approach rather than fundamental changes in device purpose or safety profile. Both devices generate automatic segmentations and volumetric data for clinical assessment by trained medical professionals, ensuring equivalent clinical utility and safety within established medical workflows.

Clinical performance testing demonstrates that the subject device performs comparably to the predicate device.

7. Performance Data

7.1. Quality and safety

The design and development of Brain WMH followed the following FDA recognized standards and guidance documents:

- ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices (#5-125)
- IEC 62304:2015 – Medical Device Software – Software Life Cycles Processes (#13-79)
- NEMA PS3 – Digital Imaging and Communications in Medicine (DICOM) Set (#12-300)
- Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May, 2005)
- Guidance for Industry and FDA Staff: Software as a Medical Devices (SaMD): Clinical Evaluation (December 2017)

Brain WMH is a software only device. Verification testing included software unit testing, software integration testing, and system testing. Testing confirmed that the software, as designed and implemented, satisfied the software requirements and has no unintentional differences from the predicate device.

7.2. Training dataset

The WMH segmentation model was trained with 474 T₂-weighted FLAIR scans collected from different geographical areas, with the majority of the data acquired in the United States. The data includes studies from 1.5 T and 3.0 T scanners from GE, Philips, and Siemens.

7.3. Performance testing

Validation of the model and software was performed using standalone performance testing, including a comparison of the subject device performance to the predicate device performance on the same dataset. The test dataset included 110 studies from 90 patients with T₂-weighted FLAIR images acquired from multiple clinical sites, with the majority of data acquired at sites in the United States. The dataset represents 1.5 T (32 studies) and 3.0 T (78 studies) scanners from GE (60 studies), Philips (39 studies) and Siemens (11 studies), and various scan settings. Scans were collected from ethnically diverse and representative male and female adult patients with age ranging from 22 to 90 years. The clinical indication for imaging was either multiple sclerosis or cognitive impairment. Scan-rescan reproducibility was conducted on a separate test set of short-interval, same-subject scan pairs. To ensure independence of the test data, the test sets were quarantined datasets not used to train or tune the model, only for software validation following internal processing aligned with good machine learning practices.

The ground truth process included multiple experts. Three experts served as truthers and one expert as an adjudicator.

Performance testing concluded that the subject device met the pre-specified performance criteria. The standalone performance of Brain WMH segmentation, as measured by Dice coefficient (0.58 ± 0.21) was higher than the standalone performance of the predicate device and fell within the range of interobserver variability. Similarly, the anatomical location labeling performance was also within the range of the interobserver performance. The longitudinal validation demonstrated high accuracy in WMH labeling across scans acquired from the same patient (97.1% correctly labelled). Additionally, scan-rescan reproducibility showed consistent volumes between short-interval, same-subject study pairs.

8. Conclusion

The verification and validation testing conducted to support this submission confirms that the subject device performs comparably to the predicate device. The minor differences between the subject and predicate device do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. Therefore, the information provided in this submission demonstrates that Brain WMH is substantially equivalent to the predicate device.