



May 13, 2026

BeauBrain Healthcare, Inc.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2552 Walnut Ave. Suite 230
Tustin, California 92780

Re: K260032

Trade/Device Name: Morph
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: April 13, 2026
Received: April 13, 2026

Dear Priscilla Chung:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 positioned over a large, light blue, semi-transparent 'FDA' watermark.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260032

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Please provide the device trade name(s).

?

Morph

Please provide your Indications for Use below.

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Morph is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. Volumetric measurements may be compared to reference percentile data.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) Summary

(K260032)

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

1. Date: 5/12/2026

2. Applicant / Submitter

BeauBrain Healthcare, Inc.
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3. U.S. Designated Agent

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4. Device Information:

- Trade/Device Name: Morph
- Common Name: Automated Radiological Image Processing Software
- Regulation Name: Medical image management and processing system
- Regulation Number: 21 CFR 892.2050
- Regulatory Class: II
- Product Code: QIH, LLZ

5. Predicate Device:

NeuroQuant (K170981) by CorTechs Labs, Inc.

6. Device Description:

Morph is an AI-powered brain MRI analysis software that provides brain quantitative assessments based on segmented quantitative information from brain MRIs. This helps medical practitioners make clinical decisions. It is an adjunctive tool and should not be used as the sole basis for final decisions or treatment.

The software automatically performs quantitative analysis of cerebrospinal fluid (CSF) volumes in cerebral areas and the lateral ventricles (LVs) to assess brain neurodegeneration, such as volumetric changes in specific brain regions. This is often associated with an increased susceptibility to neurodegenerative diseases like Alzheimer's disease (AD).

Morph is an AI-powered brain MRI analysis software that provides quantitative assessments of brain structure volumes based on segmented quantitative information from brain MRIs. This helps medical practitioners make clinical decisions. It is an adjunctive tool and should not be used as the sole basis for final decisions or treatment. The software automatically performs quantitative analysis of cerebrospinal fluid (CSF) volumes in cerebral areas and the lateral ventricles (LVs) to evaluate structural variations in specific brain regions. These quantitative measurements are compared to a reference database to support clinical interpretation.

Morph identifies the 14 specific brain regions, including the left and right CSF areas of Frontal, Occipital, Parietal, and Temporal lobes, as well as Anterior LVs, Posterior LVs, and temporal horns of LVs near the hippocampus. It uses volumetric and normative percentile data to provide standardized scores based on a large database of cognitively normal individuals.

Images in standardized DICOM format are uploaded through a web-based client software and processed by the analysis engine, which can be hosted on a cloud-based server (AWS) or an on-premises server (in-hospital). During preprocessing, the software converts 2D or 3D T1 MR images in DICOM format to NIfTI format (users can also directly upload NIfTI format images). Morph receives the MR images from either PC or PACS (or imaging modalities) through DICOM interface and then process the imaging analysis of volumetric measurements of brain structures. After the analysis is completed, the result image in the DICOM secondary capture format is saved in the PACS. Otherwise, the report can be printed out directly in PDF format.

The device is not intended to diagnose any neurodegenerative disease or brain atrophy. It is used as a quantitative tool to evaluate the patient against a reference database.

7. Indication for use:

Morph is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. Volumetric measurements may be compared to reference percentile data.

8. Substantial Equivalence:

Comparison Table

Comparison Item	Proposed Device, Morph	Predicate Device, NeuroQuant, K170981
510(k) Number	K260032	K170981
Trade Name	Morph	NeuroQuant
Design	Software as a Medical Device (SaMD)	Software as a Medical Device (SaMD)
Common Name	Medical Image Processing Software	Medical Image Processing Software
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Regulation Name	Automated Radiological Image Processing Software	Picture archiving and communications system
Regulatory Class	Class II	Class II
Product Code	QIH, LLZ	LLZ
510(k) Review Panel	Radiology	Radiology
Manufacturer	BeauBrain Healthcare Inc.	CorTechs Labs, Inc.
Target Anatomical Sites	Brain	Brain
User	Medical professionals (radiologists, neurologists and neuroradiologists)	Medical professionals (radiologists, neurologists and neuroradiologists and clinical researcher)
Indications for Use	Morph is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures from a set of MR images. Volumetric measurements may be compared to reference percentile data.	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 volumes and structures. - Automated segmentation and quantification of brain structures using deep learning-based algorithm, with MR	- Automated measurement of brain tissue volumes and structures and lesions. - Automatic segmentation and quantification of brain structures using a dynamic

Comparison Item	Proposed Device, Morph	Predicate Device, NeuroQuant, K170981
	image intensity.	probabilistic neuroanatomical atlas, with age and gender specificity, based on the MR image intensity.
Physical Characteristics	Operates in either on-premise or a cloud service environment	- Software package installed on User hardware - Operates on off-the-shelf hardware (multiple vendors)
Device Description	Morph is a fully automated MR imaging post-processing medical device software that provides automatic labeling, visualization and volumetric quantification of brain structures from a set of MR images. The resulting output is provided in a standard DICOM format as additional MR series with segmented color overlays and morphometric reports that can be displayed on third-party DICOM workstations and Picture Archive and Communications Systems (PACS). The high throughput capability makes the software suitable for use in routine patient care as a support tool for clinicians in assessment of structural MRIs.	NeuroQuant is a fully automated MR imaging post-processing medical device software that provides automatic labeling, visualization and volumetric quantification of brain structures and lesions from a set of MR images. The resulting output is provided in a standard DICOM format as additional MR series with segmented color overlays and morphometric reports that can be displayed on third-party DICOM workstations and Picture Archive and Communications Systems (PACS). The high throughput capability makes the software suitable for use in both clinical trial research and routine patient care as a support tool for clinicians in assessment of structural MRIs.
Processing Architecture	Automated internal pipeline that performs: - Segmentation - Volume calculation - Report generation	Automated internal pipeline that performs: - Artifact correction - Segmentation - Lesion quantification - Volume calculation - Report generation
Data Source	MRI scanner: 2D or 3D T1 MRI scans acquired with specified	MRI scanner: 3D T1 MRI scans acquired with specified

Comparison Item	Proposed Device, Morph	Predicate Device, NeuroQuant, K170981
	protocols • Supports DICOM format as input	protocols • Supports DICOM format as input
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 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 functions - Scan protocol verification • Results must be reviewed by a trained doctor (physician, neurologist, radiologist, clinician)	• Automated quality control functions - Tissue contrast check - Scan protocol verification - Atlas alignment check • Results must be reviewed by a trained physician

Substantial Equivalence Discussion

The proposed device, Morph is substantially equivalent to the predicate device, NeuroQuant (K170981).

Morph 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.

The predicate device is classified under 21 CFR 892.2050 (Class II, Product code LLZ), while the proposed device is classified as Automated Radiological Image Processing Software (21 CFR 892.2050, Class II, Product code QIH, Radiology). The only distinction is that the QIH product

code indicates inclusion of an AI model, whereas the LLZ product code does not; however, the devices are otherwise identical.

Indications for Use

The primary intended use of providing automatic segmentation and quantification of brain structures is equivalent. The predicate device performs volumetric quantification of brain structures including brain lesion quantification (requiring T2-FLAIR). The proposed device does not quantify brain lesions but provides volumetric analysis of anatomical brain structures from T1-weighted MR images. This difference represents a reduced functionality rather than a change in intended use. The absence of lesion quantification does not raise new questions of safety or effectiveness.

Design and Incorporated Technology

Both devices are software applications that receive T1-weighted MR images as input and provide automated brain segmentation and volumetric quantification as output. The predicate uses an atlas-based segmentation method, whereas the proposed device applies a deep learning-based segmentation model. Although the algorithmic approach differs, both rely on established image analysis technologies. AI-based algorithm(Segmentation model) Performance testing of the proposed device (DSC and ICC) demonstrates accuracy and reproducibility equivalent to the predicate, ensuring that the technological differences do not introduce new risks.

Segmentation Accuracy and Targeted Regions

Both devices produce segmentation maps with color overlays and volumetric reports. However, the predicate segments whole brain regions, including gray matter, white matter, CSF, and lesions. The proposed device segments cortical CSF regions, lateral ventricles, and hippocampal areas to quantify brain regional volume. This narrower scope is a reduced functionality but uses the same mechanism of volumetric quantification with reference percentile comparison. The omission of lesion quantification does not alter the interpretation of volumetric results and does not raise questions of safety or effectiveness.

Physical / Operational Characteristics

The predicate operates on off-the-shelf hardware, while the proposed device supports both on-premise and cloud-based environments, accessible through a web browser. This deployment difference does not affect analysis performance. Verification and validation testing confirm that the proposed device performs reliably across environments, and therefore the difference does not impact safety or effectiveness.

Quality Control Functions

The predicate device includes tissue contrast and atlas alignment checks as part of automated quality control. The proposed device, based on deep learning, does not require these checks. Instead, performance has been validated through algorithm testing, ensuring equivalent accuracy and safety. The absence of these checks does not affect the reliability of segmentation or volumetric outputs.

Output and Safety Perspective

Both devices generate segmentation maps with color overlays and quantitative volumetric reports, including percentile comparisons. The only difference is that the predicate includes lesion quantification, while the proposed device does not. For its intended function—volumetric quantification of segmentable brain structures—the proposed device provides equivalent outputs. Software validation and performance testing confirms that the device meets acceptance criteria for accuracy and reproducibility. Therefore, these differences do not raise new questions of safety or effectiveness.

Summary

The proposed device, Morph (BeauBrain Healthcare Inc.), has the same intended use and fundamental technological characteristics as the predicate device, NeuroQuant (K170981, CorTechs Labs, Inc.). Both are Software as a Medical Device (SaMD) that automatically label, visualize, and quantify brain structures from MR images, providing volumetric reports with percentile-based comparisons. Differences between the devices include the absence of lesion quantification in Morph, use of a deep learning algorithm instead of an atlas-based method, a narrower segmentation scope (CSF, ventricles, hippocampus), and the option to operate in cloud-based environments. These differences represent reduced functionality or alternative implementations rather than new intended uses. Performance testing (DSC, ICC) confirm that Morph achieves accuracy, reproducibility, and safety equivalent to the predicate. Accordingly, these differences do not raise new questions of safety or effectiveness, and Morph is therefore substantially equivalent to NeuroQuant (K170981). Accordingly, Morph is substantially equivalent to the predicate device NeuroQuant (K170981).

9. Performance Data:

The device employs an AI-based segmentation algorithm to automatically identify and quantify selected brain structures from structural MRI images, including cortical CSF spaces, lateral ventricles, and CSF spaces surrounding the hippocampal region. Performance characteristics were established through independent validation using datasets that were fully separated from the training data. These datasets were designed to reflect variability in scanner manufacturers, acquisition protocols, demographics, and clinical diagnoses.

a) Training Data

The AI-based segmentation algorithm was trained using a total of 1,947 3D T1-weighted MRI scans obtained from Samsung Medical Center (SMC) and several publicly available datasets including the IXI, ICBM, and OASIS-3.

The training dataset included adult subjects across a wide age range (50-99 years) and included both male and female subjects. The cohort also represented diverse racial groups, including White, Black, and Asian subjects. The clinically relevant groups were included, such as cognitively normal individuals, subjects with mild cognitive impairment, and patients diagnosed with Alzheimer's disease.

MRI scans were acquired using scanners from multiple major vendors including Siemens, Philips, and GE Healthcare, with magnetic field strengths of 1.5 T and 3 T and slice thicknesses of 1.0 mm and 1.2 mm. All scans consisted of 3D T1-weighted structural MRI images acquired using protocols compatible with volumetric brain analysis.

Training and validation datasets were strictly separated at the subject level. No MRI scans from the training datasets were reused in the validation datasets, ensuring independence of performance estimation.

b) Performance Testing

To support transparency of the AI-based segmentation model, the validation dataset was characterized with respect to demographics, clinical subgroups, imaging equipment, and the reference standard generation. The validation dataset consisted of 64 MRI scans from unique subjects obtained from the ADNI, a U.S.-based dataset.

The validation cohort included adult subjects aged 50–99 years, with representation across multiple age groups, including 50–59 years (6.3%), 60–69 years (31.3%), 70–79 years (32.8%), 80–89 years (28.1%), and 90–99 years (1.5%).

The dataset included female (40.6%) and male (59.4%) subjects, and the racial distribution consisted of White (89.0%), Black (6.3%), and Asian (4.7%).

In terms of clinical subgroup distribution, the cohort included cognitively normal subjects (CN) (29.7%), subjects with mild cognitive impairment (MCI) (37.5%), and patients diagnosed with Alzheimer’s disease (AD) (32.8%). MRI data were collected from multiple clinical sites across the United States, including Eastern, Western, and Midwestern regions. Images were acquired on scanners from major manufacturers, including Siemens (48.4%), GE Healthcare (31.3%), and Philips (20.3%), using 3D T1-weighted structural MRI protocols.

Imaging parameters reflected typical variability encountered in clinical practice. The dataset included images acquired with slice thicknesses of 1.0 mm (51.6%) and 1.2 mm (48.4%), and magnetic field strengths of 1.5 T (51.6%) and 3 T (48.4%).

The reference standard for segmentation accuracy evaluation was established through manual segmentation of 64 MRI scans by two U.S. board-certified neuroradiologists using predefined anatomical criteria and the ITK-SNAP software. Inter-rater agreement was assessed using the Dice Similarity Coefficient, and cases with lower agreement were reviewed by a senior neuroradiologist to establish the final consensus reference segmentation standard used for performance evaluation.

Standalone performance testing was conducted using a validation dataset consisting of 64 independent 3D T1-weighted MRI scans.

Segmentation performance was evaluated by comparing automated segmentation results with expert manual segmentations using the DSC. The predefined acceptance criterion for segmentation performance was a mean DSC greater than or equal to 0.70 across evaluated brain regions.

Dice coefficients were highest in the lateral ventricles (>0.97) and in the temporal horn adjacent to the hippocampus (>0.89). Other CSF regions demonstrated Dice coefficient ranging from approximately 0.79 to 0.82, while occipital CSF regions achieved Dice coefficients of approximately 0.71. Across the full cohort, the overall mean DSC exceeded 0.85, satisfying the predefined acceptance criteria.

To further assess the robustness and generalizability of the algorithm, additional subgroup analyses were conducted across demographic characteristics, clinical diagnosis, and imaging acquisition parameters. Mean DSC values were consistent across demographic subgroups including age and sex (0.85 to 0.88), clinical diagnostic categories including AD, MCI, and cognitively normal subjects (0.86 to 0.87), and imaging acquisition parameters including scanner manufacturer, magnetic field strength, and slice thickness (0.86 to 0.87), with no subgroup falling below the predefined acceptance criterion.

Agreement between automated and expert reference volumetric measurements was evaluated using Bland–Altman analysis. Mean bias, standard deviation of volume differences, and 95% limits of agreement (LoA) were assessed for all evaluated brain regions. In ventricular regions, mean bias ranged from -30.8 mm^3 to 138.4 mm^3 , with standard deviations ranging from 62.6 mm^3 to 478.5 mm^3 and 95% LoA ranging from -799.6 mm^3 to 1076.3 mm^3 . In lobar regions, mean bias ranged from approximately $-2,071 \text{ mm}^3$ to 223 mm^3 , with standard deviations ranging from 318.1 mm^3 to 5105.5 mm^3 and 95% LoA ranging from -12078.2 mm^3 to 7935.3 mm^3 . These results demonstrated low volumetric bias and agreement within predefined clinically acceptable 95% LoA ranges between automated and expert reference measurements, with no evidence of clinically significant systematic bias.

Summary

The proposed device, Morph (BeauBrain Healthcare Inc.), has the same intended use and similar fundamental technological characteristics as the predicate device, NeuroQuant (CorTechs Labs, Inc.). Both devices are Software as a Medical Device (SaMD) that automatically segment, visualize, and quantify brain structures from MR images and generate volumetric reports with percentile-based comparisons.

Differences include the use of a deep learning–based segmentation algorithm in Morph, a narrower segmentation scope, the absence of lesion quantification, and the option for cloud-based deployment. These differences do not introduce new intended uses or raise new questions of safety or effectiveness.

Performance testing demonstrated that Morph provides accurate and reproducible volumetric measurements comparable to those of the predicate device. Therefore, Morph is substantially equivalent to the predicate device.

10. Conclusion:

The subject device is substantially equivalent in the areas of technical characteristics, general

function, application, and indications for use. The test results also support the substantial equivalence to the predicate devices. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.