



August 22, 2025

Galileo CDS, Inc
% David Giese
Partner
Innolitics LLC
1101 West 34th Street #550
Austin, Texas 78705

Re: K252362
Trade/Device Name: GBrain MRI
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: July 24, 2025
Received: July 29, 2025

Dear David Giese:

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 large, light blue '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

Submission Number (if known)

K252362

Device Name

GBrain MRI

Indications for Use (Describe)

GBrain MRI is a post processing medical device software intended for analyzing and quantitatively reporting signal hyperintensities in the brain on T2w FLAIR MR images and T1w post contrast images in the context of diagnostic radiology.

GBrain MRI is intended to provide automatic segmentation, quantification, and reporting of derived image metrics. It is not intended for detection or specific diagnosis of any disease nor for the detection of signal hyperintensities.

GBrain MRI should not be used in-lieu of a full evaluation of the patient's MRI scans. The physician retains the ultimate responsibility for making the final patient management and treatment decisions.

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
PRASStaff@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	
		Page 1 of 11

K252362

1. CONTACT INFORMATION

Company Name	Galileo CDS, Inc
Address	7000 N Mopac Expy, Suite 200, Austin, TX 78731
Phone Number	(512) 222-9173
Company Representative	Abhijeet Pradhan
Email	ap@galileocds.com
Primary Contact	David Giese
Primary Contact Phone Number	+1.913.523.6988
Primary Contact Email	fda@innolitics.com
Date Summary Prepared	August 18, 2025

2. DEVICE INFORMATION

Trade Name: GBrain MRI

Common Name: Brain MRI Image Processing Software

Classification Name: Automated Radiological Image Processing Software

Regulation Number: 21 CFR 892.2050

Product Code(s): QIH, LLZ

3. PREDICATE DEVICE

Predicate Device Name	GBrain MRI
Manufacturer	Galileo CDS Inc
510(k) Number	K250416
Product Code	QIH, LLZ
Regulation Number	21 CFR 892.2050

	510(k) Summary	
		Page 2 of 11

Regulation Name	Medical image management and processing system
Regulatory Class	Class II
Review Panel	Radiology

4. DEVICE DESCRIPTION

4.1. Description

GBrain MRI is a non-invasive MR imaging post-processing medical device software that aids in the volumetric quantification of hyperintensities in T2-weighted Fluid Attenuated Inversion Recovery (T2w FLAIR), and in post contrast T1-weighted (T1c) brain MR images. It is intended to aid the trained radiologist in quantitative measurements.

The input to the software are the T2w FLAIR and the T1w post contrast brain MR images.

The outputs are volume measurements in Secondary Capture DICOM format, a DICOM Encapsulated pdf file, as well as a DICOM SR. More specifically, the total volume of hyperintensities in the input T2w FLAIR and the T1c are shown in two new secondary capture image series, called GBrain T2 FLAIR & GBrain T1 CE respectively, with a segmentation overlay on the hyperintensities that were used to measure the total volumes. These volume measurements are summarized in the DICOM encapsulated pdf and DICOM SR files.

The outputs are provided in standard DICOM format that can be displayed on most third-party DICOM workstations and Picture Archive and Communications Systems (PACS).

The software is suitable for use in routine patient care as a support tool for radiologists in assessment of structural adult brain MRIs, by providing them with complementary quantitative information.

The GBrain MRI processing architecture includes a proprietary automated internal pipeline that performs skull stripping, signal normalization, segmentations, volume calculations, and report generation.

From a workflow perspective, GBrain MRI is packaged as a computing appliance that is capable of supporting DICOM file transfer for input, and output of results. The software is designed without the need for a user interface after installation. Any processing errors are reported either in the output series report, or in the system log files.

	510(k) Summary	
		Page 3 of 11

GBrain MRI software is intended to be used by trained personnel only and is to be installed by trained technical personnel.

Quantitative reports and derived image data sets are intended to be used as complementary information in the review of a case.

The GBrain MRI software does not have any accessories or patient contacting components. The GBrain MRI device is intended to be used for the adult population only.

5. SUBJECT DEVICE INDICATIONS FOR USE

GBrain MRI is a post processing medical device software intended for analyzing and quantitatively reporting signal hyperintensities in the brain on T2w FLAIR MR images and T1w post contrast images in the context of diagnostic radiology.

GBrain MRI is intended to provide automatic segmentation, quantification, and reporting of derived image metrics. It is not intended for detection or specific diagnosis of any disease nor for the detection of signal hyperintensities.

GBrain MRI should not be used in-lieu of a full evaluation of the patient's MRI scans. The physician retains the ultimate responsibility for making the final patient management and treatment decisions.

5.1. Subject Device Contraindications for Use

GBrain MRI is contraindicated for use in pediatric patient populations, and in patients who have undergone brain tumor or other resection surgery.

5.2. Subject Device Intended Use

GBrain MRI is a post processing medical device software intended for analyzing and quantitatively reporting signal hyperintensities in the brain on T2w FLAIR MR images and T1w post contrast images in the context of diagnostic radiology.

GBrain MRI is intended to provide automatic segmentation, quantification, and reporting of derived image metrics. It is not intended for detection or specific diagnosis of any disease nor for the detection of signal hyperintensities.

GBrain MRI should not be used in-lieu of a full evaluation of the patient's MRI scans. The

	510(k) Summary	
		Page 4 of 11

physician retains the ultimate responsibility for making the final patient management and treatment decisions.

6.SUBSTANTIAL EQUIVALENCE COMPARISON

6.1. Predicate Device Indications for Use

GBrain MRI is a post processing medical device software intended for analyzing and quantitatively reporting signal hyperintensities in the brain on FLAIR MR images in the context of diagnostic radiology.

GBrain MRI is intended to provide automatic segmentation, quantification, and reporting of derived image metrics. It is not intended for detection or specific diagnosis of any disease nor for the detection of signal hyperintensities.

GBrain MRI should not be used in-lieu of a full evaluation of the patient's MRI scans. The physician retains the ultimate responsibility for making the final patient management and treatment decisions.

6.2. Subject Device Indications for Use

GBrain MRI is a post processing medical device software intended for analyzing and quantitatively reporting signal hyperintensities in the brain on T2w FLAIR MR images and T1w post contrast images in the context of diagnostic radiology.

GBrain MRI is intended to provide automatic segmentation, quantification, and reporting of derived image metrics. It is not intended for detection or specific diagnosis of any disease nor for the detection of signal hyperintensities.

GBrain MRI should not be used in-lieu of a full evaluation of the patient's MRI scans. The physician retains the ultimate responsibility for making the final patient management and treatment decisions.

6.3. Indications for Use Equivalence Discussion

The intended use of all of the devices is the same - analyzing and evaluating neurological imaging data. The indications are equivalent to the scope of regulation 21 CFR 892.2050.

The indications for use of the Subject Device are substantially equivalent to those of the Predicate device.

The output of the Predicate Device (GBrain MRI, K250416) consists of segmentations, visualizations and volumetric measurements of hyperintense signal on T2w FLAIR MRI. The Predicate Device has a general indication for use and is not specific to a target disease or condition.

The Subject Device's indications for use are identical to the Predicate with only the addition of post-contrast T1w MRI images, similar to the Reference Device.

To elaborate further, the Subject and the Predicate device share the intended use of automated quantification of MR signal hyperintensity in the context of diagnostic radiology.

The shared technical tasks performed by the Subject and Predicate Device, with regard to the measurement of hyperintensities are exactly the same.

6.4. Device Comparison Table

Feature/Function	GBrain MRI	Predicate GBrain MRI (K250416)	Comments on Substantial Equivalence
510K Number	N/A	K250416	-
Manufacturer	Galileo CDS Inc	Galileo CDS Inc	-
Classification	Class II	Class II	Same
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Same
Regulation Description	Medical image management and processing system.	Medical image management and processing system.	Same
Classification Name	Automated Radiological Image Processing Software	Automated Radiological Image Processing Software	Same
Product code	QIH, LLZ	QIH, LLZ	Same
Intended Use	MR imaging data post processing software	MR imaging data post processing software	Same
Type of Imaging Scan	MRI	MRI	Same
Intended Body Part	Brain	Brain	Same

Feature/Function	GBrain MRI	Predicate GBrain MRI (K250416)	Comments on Substantial Equivalence
Indications for Use	GBrain MRI is a post processing medical device software intended for analyzing and quantitatively reporting signal hyperintensities in the brain on T2w FLAIR MR images and T1w post contrast images in the context of diagnostic radiology. GBrain MRI is intended to provide automatic segmentation, quantification, and reporting of derived image metrics. It is not intended for detection or specific diagnosis of any disease nor for the detection of signal hyperintensities. GBrain MRI should not be used in-lieu of a full evaluation of the patient's MRI scans. The physician retains the ultimate responsibility for making the final patient management and treatment decisions.	GBrain MRI is a post processing medical device software intended for analyzing and quantitatively reporting signal hyperintensities in the brain on FLAIR MR images in the context of diagnostic radiology. GBrain MRI is intended to provide automatic segmentation, quantification, and reporting of derived image metrics. It is not intended for the detection or specific diagnosis of any disease nor for the detection of signal hyperintensities. GBrain MRI should not be used in-lieu of a full evaluation of the patient's MRI scans. The physician retains the ultimate responsibility for making the final patient management and treatment decisions.	The indications for use are identical to the predicate device with the addition of post-contrast images. The subject device analyzes signal hyperintensities regardless of location similar to the predicate. As with the predicate, the subject device has a general indication and is not specific to a particular disease or condition.
Environment for use	Hospital, Clinic, Imaging Center, Medical Offices	Hospital, Clinic, Imaging Center, Medical Offices	Same as Predicate
Intended Patient Population	Adult patients aged 21 and above with a brain MRI study.	Adult patients aged 21 and above with a brain MRI study.	Same as Predicate
Intended User	Radiologists, Imaging Professionals, and other Clinicians working with radiological images. The application should be used as a support tool in assessment of structural MRIs. Patient management decisions should not be based solely on the results of the device.	Radiologists, Imaging Professionals, and other Clinicians working with radiological images. The application should be used as a support tool in assessment of structural MRIs. Patient management decisions should not be based solely on the results of the device.	Same as Predicate

	510(k) Summary	
		Page 7 of 11

Feature/Function	GBrain MRI	Predicate GBrain MRI (K250416)	Comments on Substantial Equivalence
Design and Incorporated Technology	Automated segmentation using deep learning followed by volume calculations, and report generation. Results displayed on PACS.	Automated segmentation using deep learning followed by volume calculations, and report generation. Results displayed on PACS.	Same as Predicate
Physical Characteristics	Software package- Operates on off-the-shelf hardware (multiple vendors).	Software package- Operates on on off-the-shelf hardware (multiple vendors).	Same as Predicate
Data Source	Supports DICOM format as input from the MRI scanner or the PACS.	Supports DICOM format as input from the MRI scanner.	Same as Predicate
Output	Provides volumetric measurements of regions with hyperintense signal on T2w FLAIR and post contrast T1w images. Includes segmented color overlays and volumetric reports	Provides volumetric measurements of regions with hyperintense signal on T2w FLAIR images. Includes segmented color overlays and volumetric reports	The subject device extends the functionality of the predicate device to include the measurement of contrast enhancing regions on T1w images.
Reporting	Results displayed in text and graphical formats	Results displayed in text and graphical formats	Same as Predicate
DICOM Communication	Yes	Yes	Same as Predicate
Safety	Automated quality control function: scan protocol verification. Results must be reviewed by a clinician with proper training.	Automated quality control function: scan protocol verification. Results must be reviewed by a clinician with proper training.	Same as Predicate

6.5. Summary of Technological Characteristics Comparison

The Subject and Predicate device has very similar technological characteristics. Both devices are software only medical devices. The inputs for both devices are Brain MRI images in DICOM format. The outputs from both devices are automatically generated in DICOM format.

Both the devices use deep learning to segment hyperintensities in FLAIR MR images, and subsequently calculate the volumes of these regions. The Subject Device also segments hyperintensities, i.e. contrast enhancing regions, on T1w post contrast MR images. In both devices, these segmentations are overlaid as colored regions on DICOM images for users to visualize the regions used in the volume calculations.

All the devices also summarize these measurements and present them in a pdf document. In summary, both devices have extremely similar technological characteristics.

7. DISCUSSION OF PERFORMANCE TESTING

Performance testing included protocols demonstrating the similarity of automated segmentation compared to manual radiologist segmentations. The GBrain MRI segmentation performance was evaluated by comparing the software-derived segmentations to a Simultaneous Truth and Performance Level Estimation (STAPLE) algorithm generated consensus of three expert-labeled segmentations of hyperintensities for volume measurement accuracy, and segmentation overlap agreement. Comparisons to expert segmentations were quantified using OLS Regression, and Dice similarity coefficient (extent of software-derived vs. ground truth overlap). The three expert labeled segmentations were performed by three independent US board certified, experienced neuroradiologists.

Contrast Enhancement measurements were validated on 131 patient cases. These cases were collected from four separate hospital systems based in Alabama, Florida, Kentucky, and California to ensure geographic diversity and reasonable similarity to the broader US patient population, as well as adequate coverage of MRI manufacturers, models, and acquisition protocols. This external dataset used for validation was independent from the internal training datasets. Acceptance criteria were set at clinically acceptable levels.

Distribution of Validation cases across Age, Gender, and Ethnicity are shown in the tables below.

Age	T1w Post Contrast Cases
19-45	18
46-92	70

	510(k) Summary	
		Page 9 of 11

Age	T1w Post Contrast Cases
Unknown/Missing	43

Gender	T1w Post Contrast Cases
Female	68
Male	52
Unknown/Missing	11

Ethnicity/Race	T1w Post Contrast Cases
White	99
Black	11
Latino	4
Asian	5
Unknown/Missing/Other	12

Distribution of Validation cases across Manufacturer and Field Strength are shown in the tables below.

Manufacturer	T1w Post Contrast Cases
GE	30
Philips	41
Siemens	59

Field Strength	T1w Post Contrast Cases
1.5T	73
3T	40

Field Strength	T1w Post Contrast Cases
Unknown	18

The lower bound for the 95% CI for R2 on volume measurement was 0.94 for Contrast Enhancement, while the lower bound of the 95% CI for DICE was 0.81. Reproducibility testing showed R2 value of 0.92.

GBrain performance generally increased with increase in size and brightness of the hyperintensity measured. Hyperintensity brightness was measured as a Z score, measuring the brightness of the hyperintensity as compared to the rest of normal brain tissue. The performance of GBrain for FLAIR and Contrast Enhancement measurements is shown in the tables below.

Contrast Enhancement Measurement performance related to Hyperintensity Size

Volume (cm3)	R2	Median DICE
Small less than 4.2 cm3	0.68	0.73
Between 4.2-64.9 cm3	0.90	0.85

Contrast Enhancement Measurement performance related to Hyperintensity Brightness

Z-score	R2	Median DICE
0 – 1.49	0.87	0.69
1.5 – 1.99	1.00	0.79
2.0 – 2.99	0.96	0.81
3.0+	0.94	0.87

The results of the segmentation performance testing demonstrated that the GBrain MRI system segments hyperintensities with an accuracy that passed the planned acceptance criteria. It is concluded that GBrain MRI segmentation is sufficiently accurate to be used in clinical practice in accordance with its indications for use.

7.1. Conclusion

The comparison between the two devices demonstrates that GBrain MRI is as safe and as effective as its predicates. The devices have substantially equivalent intended uses, intended users, and principles of operation. They have the same basic design, functions, and technological

	510(k) Summary	
		Page 11 of 11

characteristics. V&V testing demonstrated that the subject device performed with similar accuracy and reliability as the predicate device to meet its intended use specifications.

Therefore, GBrain MRI is substantially equivalent to its predicate devices without raising any new concerns relating to safety or effectiveness.