GE Medical Systems SCS
Indu Karun
Regulatory Affairs Leader
283 rue de la Miniere
78530 Buc
Buc, 78530, France

January 25, 2024

Re: K233714
Trade/Device Name: BreView
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: November 20, 2023
Received: November 20, 2023

Dear Indu Karun:

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.

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,

Jessica Lamb

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233714

Device Name

BreView

Indications for Use *(Describe)*

BreView is a tool to aid clinicians with the review of multi-parametric breast magnetic resonance (MR) images. The combination of acquired images, reconstructed images, annotations, and measurements performed by the clinician are intended to provide the referring physician with clinically relevant information that may aid in diagnosis and treatment planning.

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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510K SUMMARY

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	November 20, 2023
Submitter:	GE Medical Systems SCS Establishment Registration Number - 9611343 283 rue de la Miniere 78530 Buc, France
Primary Contact Person:	Indu Karun Regulatory Affairs Leader GE HealthCare Tel: 262-232-2055 Email: Indu.Karun@ge.com
Secondary Contact Person:	Camille Vidal Senior Director Regulatory Affairs GE HealthCare Tel: 240-280-5356 Email: Camille.Vidal@ge.com
Device Trade Name:	BreView
Common/Usual Name:	BreView
Primary Regulation Number: Primary Product Code: Classification:	Medical image management and processing system (21 CFR 892.2050) LLZ Class II
Primary Predicate Device Device name: Manufacturer: 510(k) number: Primary Regulation Number: Product Code: Classification:	 READY View GE Medical Systems SCS K113456 21 CFR 892.2050 Medical image management and processing system LLZ Class II

Reference Device	
Device name:	Integrated Registration
Manufacturer:	GE Medical Systems SCS
510(k) number:	K093234
Primary Regulation Number:	21 CFR 892.2050 Medical image management and processing system
Product Code:	LLZ
Classification:	Class II

Device Description:

BreView is a dedicated advanced visualization review and post-processing tool that facilitates optimized post-processing of MR breast data review and assessment workflows for radiologists - including organizing images and composing reports. Adding the techniques of automatic motion correction and subtraction improves the review process. Software functionalities include:

- Ability to load 2D, 3D and 4D MR datasets as well as DICOM Secondary Captures (SCPT)
- Optimized display of multi-parametric images within a dedicated layout
- Display customization: ability to choose layout, orientation, rendering mode
- Guided workflows for reviewing and processing MR breast exams
- Automated motion correction and/or subtraction of multi-phase datasets
- Multi-planar reformats and maximum intensity projections (MIPs)
- Semi-automated segmentation and measurement tools
- Graph view for multi-phase datasets
- Save and export capabilities though DICOM Secondary Captures
- Data export in the form of a summary table

Intended Use:

BreView is a medical diagnostic software intended for use by trained healthcare professionals. The clinician remains ultimately responsible for the final assessment and diagnosis based on state-of-the-art practices, clinical judgment and interpretation of breast MR images or quantitative data.

Indication for Use:

BreView is a tool to aid clinicians with the review of multi-parametric breast magnetic resonance (MR) images. The combination of acquired images, reconstructed images, annotations, and measurements performed by the clinician are intended to provide the referring physician with clinically relevant information that may aid in diagnosis and treatment planning.

Technology:

The proposed device BreView employs the same fundamental scientific technology as its predicate device.

Comparison:

The table below summarizes the key feature/technological differences and similarities between the predicate devices:

Specification	**Predicate Device** **READY View (K113456)**	**Subject Device: BreView**	**Comparison**
Indications for Use	READY View is an image analysis software that allows the user to process dynamic or functional volumetric data and to generate	BreView is a tool to aid clinicians with the review of multi-parametric breast magnetic resonance (MR)	**Equivalent.** Both the predicate and proposed device are intended to display and

Specification	**Predicate Device** **READY View (K113456)**	**Subject Device: BreView**	**Comparison**
	maps that display changes in image intensity over time, echo time, b-value (Diffusion imaging) and frequency (Spectroscopy). The combination of acquired images, reconstructed images, calculated parametric images, tissue segmentation, annotations and measurement performed by the clinician allows multi-parametric analysis and may provide clinically relevant information for diagnosis.	images. The combination of acquired images, reconstructed images, annotations, and measurements performed by the clinician are intended to provide the referring physician with clinically relevant information that may aid in diagnosis and treatment planning.	process multi-parametric MR images. While READY View is intended for use on several anatomies, BreView is intended for breast exams only, thus BreView has a narrower indication for use than READY View.
Computational Platform	AW Server (K081985) platform with Volume Viewer (K041521) also known as VVApps framework. User accesses the application through networked computer equipped with the compatible thick client or through a web browser.	AW Server platform leveraging the user interface elements and functionalities of the Imaging Source Viewer and Imaging Fabric. User accesses the application through a web browser on networked computers.	**Equivalent.** Both applications are server based and accessible through connected computer. The VV Apps framework is replaced by modernized software elements with equivalent user layout and image rendering and ROI editing tools.
Compatible MR series	DICOM format MR series including 2D, 3D and 4D (temporal series)	DICOM compliant MR series including 2D, 3D and 4D MR series. Type of MR exams the application takes as input: (motion-corrected and/or subtracted) T1 – weighted DCE sequences, T1 – weighted series, T2 – weighted series, diffusion weighted (DWI) series and ADC maps.	**Identical**
Non-rigid registration for motion correction (NRR)	Non-rigid motion correction based on ROI groupwise registration.	Non-rigid motion correction based on ROI groupwise registration.	**Identical** The non-rigid registration uses the same method as that of Integrated Registration (K093234) for the registration of MR series.

Specification	**Predicate Device** **READY View (K113456)**	**Subject Device: BreView**	**Comparison**
Image Subtractions	As part of Breast review protocol, the first acquisition of the DCE series is used as baseline. Subsequent phase acquisitions are subtracted from the baseline after registration.	Same as READY View with the possibility to apply subtraction without applying non-rigid registration.	**Equivalent** Both proposed and predicate devices enable image subtraction although the proposed device allows the user to apply image subtraction without NRR registration while the predicate only allow subtraction after registration.
Multi-planar reformats and MIP	READY View is a unified and comprehensive advanced visualization and analysis solution that displays 2D, 3D and 4D images of human anatomy, creates multi-planar reformatting, image subtraction, time intensity curves, processes functional curves and maps from MR data sets and performs tissue segmentation from anatomical or parametric images.	BreView uses rendering methods from Imaging Fabric including, amongst others Native, MPR (Multi-Planar Reformation), MIP (Maximum Intensity Projection), VR (Volume Rendering).	**Equivalent** Imaging Fabric rendering methods are used in cleared applications like CardIQ Suite (K213725)
Smart brush tool for enhanced segmentation volumetric assessment	Auto contour is a semi-automated segmentation tool for delineation of regions of interest. This is a functionality of Volume Viewer (K041521) It creates a semi-automated contour with a defined pixel threshold based on a user click within the region of interest.	Brush tools are semi-automatic segmentation algorithms. Two brush types are available in BreView that enable the segmentation of a region of interest based on a user click: Smart Brush and Threshold Brush.	**Equivalent**, both the predicate and proposed device include semi-automated contouring tools to allow the user to select region of interest in the image. In both applications the user can adjust the sensitivity of the brush to intensity distribution in the image.
Graph View	Graphical representation of pixel values in the temporal series, for a cursor position, or for the pixel values within one or more regions of interest (ROI) defined on the views by the user.	Graph Viewport displays a line plot representing statistics computed on a temporal series representing signal intensity evolution of defined regions of interest at different phases.	**Equivalent** Both applications have the capability to display in a graphical form the temporal variation of pixel values in a temporal series.
Data Export	DICOM Secondary Capture export	DICOM Secondary Capture export	**Equivalent** Both the predicate and proposed device have capabilities to export the

Specification	Predicate Device READY View (K113456)	Subject Device: BreView	Comparison
		Copy viewports content and findings to Clipboard for further pasting.	information displayed in the application.

Determination of Substantial Equivalence:

Summary of Non-Clinical, Design Control Testing

BreView has successfully completed the design control testing per GE HealthCare's quality system. It was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The proposed device complies with NEMA PS 3.1 - 3.20 (2022) Digital Imaging and Communications in Medicine (DICOM) Set (Radiology) standard.

The following quality assurance measures were applied to the development of the device:

- Requirements Definition
- Risk Analysis
- Technical Design Reviews
- Formal Design Reviews
- Software Development Lifecycle
- Performance testing (Verification, Validation)
- Safety Testing (Verification)

The proposed BreView application has been successfully verified and validated on the AW Server. The documentation level was determined to be Basic Documentation Level.

Bench testing was conducted on a database of exams representative of the clinical scenarios where BreView is intended to be used, with consideration of acquisition protocols and clinical indicators. BreView Non-Rigid Registration algorithm was tested and found to be successfully implemented. End user evaluation of the brush revealed that its behavior was equivalent or better to that of AutoContour (VV Apps K041521)

Conclusion:

BreView has substantial equivalent technological characteristics as its predicate device.

Based on development under GE HealthCare's quality system, successful design verification and validation, software documentation for Basic Level of Documentation, along with the engineering bench testing GE HealthCare believes that the proposed BreView is substantially equivalent to, and hence as safe and as effective for its Intended Use as the legally marketed predicate device.