March 24, 2026

GE Medical Systems SCS
Fayçal Kherra
Senior Regulatory Affairs Program manager
283 Rue De La Miniere
Buc, 78530
France

Re: K260087
Trade/Device Name: Senographe Pristina; SenoBright HD; Pristina Serena; Pristina Serena Bright
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-Field Digital Mammography System
Regulatory Class: Class II
Product Code: MUE
Dated: January 9, 2026
Received: January 12, 2026

Dear Fayçal Kherra:

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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260087

Device Name
Senographe Pristina; SenoBright HD; Pristina Serena; Pristina Serena Bright

Indications for Use *(Describe)*
Senographe Pristina : The Senographe Pristina system is intended to be used in the same clinical applications as traditional mammographic film/screen systems. It generates digital mammographic images which can be used for screening and diagnosis of breast cancer.

SenoBright HD: SenoBright HD is an extension of the existing indication for diagnostic mammography with Senographe Pristina. The SenoBright application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and ultrasound exams to help localize a known or suspected lesion

Pristina Serena:The Pristina Serena option provides the three-dimensional location of target lesions, using information obtained from stereotactic pairs of two-dimensional X-ray images. This information provides guidance for a variety of minimally invasive or interventional procedures in the breast such as: vacuum assisted biopsy, core biopsy, pre-surgical localization (e.g. hookwire), and fine needle aspirations (FNA).

Pristina Serena Bright: The Pristina Serena Bright option provides the three-dimensional location of target lesions, using information obtained from stereotactic pairs of two-dimensional X-ray images acquired with Contrast Enhanced Spectral Mammography (CESM) under the same breast compression. This information provides guidance for a variety of minimally invasive or interventional procedures in the breast such as: vacuum assisted biopsy, core biopsy, pre-surgical localization (e.g. hookwire), and fine needle aspirations (FNA). CESM-Biopsy application is indicated for patients with suspicious lesions only seen with certainty when imaged with a contrast agent or that do not have a definite correlate on mammography or ultrasound

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.

510(k) Summary – K260087

Device Trade Name:	**Senographe Pristina™** **SenoBright™ HD** **Pristina Serena™** **Pristina Serena Bright™**
Submitter:	GE Medical Systems SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE
Primary Contact Person:	Fayçal Kherra, Senior Regulatory Affairs Program Manager, GE Medical Systems SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE Phone: +33 (1) 30704040 Email: Faycal.kherra@gehealthcare.com
Secondary Contact Person:	Gregory Pessato Regulatory Affairs Director GE Medical Systems SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE Phone: +33 (6) 34423240 Email: GregoryPessato@gehealthcare.com
Device Classification Name: Classification: Device Product Code: Regulation Number: Regulation Name	Full Field Digital, System, X-Ray, Mammographic Class II MUE 21CFR 892.1715 Full-Field Digital Mammography System
Predicate Device	Senographe Pristina cleared under 510(k) number K211725 Regulation Name: Full-Field Digital Mammography System: 21CFR 892.1715 Classification: Class II Product Codes: MUE
Device Description:	**Senographe Pristina** (Full Field Digital Mammography) Senographe Pristina is a full field digital mammography system intended for breast cancer screening and diagnostic mammography. The system acquires two dimensional (2D) digital mammography images and provides on screen image display, archiving, networking, and filming capabilities. It incorporates a large detector enabling imaging of large breasts, adjustable paddles for

	positioning smaller breasts, and system adjustments to support patient positioning during standard mammography examinations. **SenoBright HD** (Contrast Enhanced Spectral Mammography – CESM) SenoBright HD is the CESM configuration of the Senographe Pristina platform. CESM acquires paired low-energy (LE) and high-energy (HE) images following intravenous administration of an iodinated contrast agent. From these acquisitions, the system generates recombined iodine-specific images to assist in the assessment of suspicious lesions. **Pristina Serena** (Stereotactic Biopsy – 2D) Pristina Serena is a stereotactic biopsy accessory used with the Senographe Pristina imaging platform. The Biopsy Positioner mounts onto the system in place of the Bucky and supports vertical and horizontal biopsy approaches. It includes a needle holder compatible with various needle guides, enabling precise lesion targeting based on 2D angled mammographic views. **Pristina Serena Bright** (CESM Guided Biopsy) Pristina Serena Bright is a CESM guided biopsy option used with Pristina Serena. It acquires paired low-energy and high energy images to produce both conventional mammographic images and iodine specific images to guide biopsy for contrast enhancing lesions. **Scope of this 510(k):** The currently cleared post-processing algorithm, eContrast, converts DICOM "for processing" images into DICOM "for presentation" images by optimizing local contrast, reducing global dynamic range, and improving the visualization of structures within the breast. This 510(k) introduces MV processing, an updated image post-processing algorithm. MV processing maintains the same fundamental image-processing workflow and principles as eContrast and provides refinements intended to improve consistency of image appearance across patients. MV offers seven selectable image-processing settings (MV1 through MV5, MVImplant, and MVS). MV processing applies only to 2D images of Senographe Pristina, 2D images of Pristina Serena, low-energy images of SenoBright HD and low-energy images of Pristina Serena Bright. **Cumulative Changes** This 510(k) also consolidates cumulative modifications implemented since clearance of the previous configuration (K211725). These updates include workflow and usability improvements, interoperability enhancements, and minor hardware adjustments that do not change the intended use, indications for use, safety, or essential performance.
Intended Use:	**Senographe Pristina**: The Senographe Pristina system is intended for screening and diagnostic mammography.

	SenoBright HD: SenoBright HD is an extension of the existing indication for diagnostic mammography with Senographe Pristina. The SenoBright HD application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and ultrasound exams to help localize a known or suspected lesion. **Pristina Serena**: Pristina Serena is an optional accessory of Senographe Pristina intended to provide accurate location of lesions in the breast in three dimensions. **Pristina Serena Bright:** Pristina Serena Bright is an optional accessory of Senographe Pristina intended to provide accurate location of lesions in the breast in three dimensions. *Note: The intended use is unchanged from the predicate.*
Indications for Use:	**Senographe Pristina**: The Senographe Pristina system is intended to be used in the same clinical applications as traditional mammographic film/screen systems. It generates digital mammographic images which can be used for screening and diagnosis of breast cancer. **SenoBright HD**: SenoBright HD is an extension of the existing indication for diagnostic mammography with Senographe Pristina. The SenoBright application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and ultrasound exams to help localize a known or suspected lesion **Pristina Serena**: The Pristina Serena option provides the three-dimensional location of target lesions, using information obtained from stereotactic pairs of two-dimensional X-ray images. This information provides guidance for a variety of minimally invasive or interventional procedures in the breast such as: vacuum assisted biopsy, core biopsy, pre-surgical localization (e.g. hookwire), and fine needle aspirations (FNA). **Pristina Serena Bright**: The Pristina Serena Bright option provides the three-dimensional location of target lesions, using information obtained from stereotactic pairs of two-dimensional X-ray images acquired with Contrast Enhanced Spectral Mammography (CESM) under the same breast compression. This information provides guidance for a variety of minimally invasive or interventional procedures in the breast such as: vacuum assisted biopsy, core biopsy, pre-surgical localization (e.g. hookwire), and fine needle aspirations (FNA). CESM-Biopsy application is indicated for patients with suspicious lesions only seen with certainty when imaged with a contrast agent or that do not have a definite correlate on mammography or ultrasound *Note: The Indications for use are not changed.*

Technology:

Comparison of Subject Devices with MV Processing and Cumulative Changes to the Predicate Device (Senographe Pristina with eContrast, K211725) and Reference Devices (Pristina Serena K173576, Seno-Bright HD K211215, Pristina Serena Bright K193334)	
Main Image chain elements	The subject devices use the same X-ray tube, anti-scatter grid, generator, filters, collimation, automatic exposure control, and gantry configuration as the predicate device. No changes were introduced to any component of the X-ray generation or acquisition chain.
Detector	The detector technology remains identical, with the same active area and pixel size as the predicate. The subject device includes additional detector coating and uses an updated gain module.
Control station	The predicate device uses a fixed-height control station. The subject device adds an adjustable-height control station option and introduces RFID-based login/logout capability, while maintaining otherwise equivalent control-station functionalities.
Operating system	The subject device uses an updated operating system.
Breast Support Components:	The bucky and the biopsy positioner retain the same structural design and material composition as the predicate device. For localization accessories, the subject device maintains the existing paddles and introduces two additions: a small pre-surgical localization paddle and a laser crosshair used to support localization alignment.
Biopsy device compatibility	The subject device maintains all predicate biopsy-device compatibility and adds support for additional systems, including ATEC and Brevera.
Image Pre-Processing (RAW image generation)	The image pre-processing chain remains the same. The subject device incorporates an updated gain-correction method based on an improved registration approach.
Image Post-Processing (PROCESSED image generation)	The predicate device uses the eContrast algorithm with six selectable levels. The subject device introduces the MV post-processing algorithm, which updates several existing processing levels, and adds a new level. MV processing applies only to 2D images of Senographe Pristina, 2D images of Pristina Serena, low-energy images of SenoBright HD and low-energy images of Pristina Serena Bright.
CESM Routine Image Processing (SenoBright HD) (RECOMBINED image generation)	The Recombined image-processing chain for CESM routine imaging remains unchanged compared to the previously cleared configuration.

Test Summary:	Senographe Pristina; SenoBright HD; Pristina Serena and Pristina Serena Bright with MV processing have successfully completed all required design control testing in accordance with GE HealthCare's quality management system. No unexpected results were observed. The design change was developed and will be manufactured under the Quality System Regulations of 21 CFR 820 and ISO 13485. The following quality assurance measures were applied to the development: • Risk Analysis • Design Reviews • Software Development Lifecycle • Safety and effectiveness testing at component level (Standard verification) • Safety and effectiveness testing at system level (Standard verification) • Additional testing to support substantial equivalence and image acceptability (Additional Performance Testing) **Standard Verification Testing** The safety and performance of Senographe Pristina with the updated image processing algorithm were demonstrated through full verification testing. Specifically, Verification testing included scoring of FFDM and 2D Biopsy images of standard mammography phantom. Results demonstrated that performance and safety requirements with MV processing are met. Note: These tests cover SenoBright HD and Serena Bright, since the low-energy images are the same as standard 2D and 2D-biopsy images acquired with Senographe Pristina and Pristina Serena, respectively. **Additional Performance Testing** Additional performance testing was conducted in accordance with the FDA guidance "Class II Special Controls Guidance Document: Full Field Digital Mammography System" (November 5, 2013). Testing included bench and clinical evaluations using representative digital mammography images acquired under clinically relevant imaging conditions. • **Phantom Testing**: Two complementary phantom studies were performed to evaluate image quality performance and demonstrate substantial equivalence between MV and eContrast algorithms. Testing was performed using identical image datasets processed with both MV and the predicate eContrast algorithms, enabling direct comparative assessment. Image datasets encompassed a range of exposure levels and imaging scenarios representative of screening and diagnostic mammography. - **Detectability Testing**: A four-alternative forced-choice detection task was conducted to assess for a potential detectability performance difference between eContrast and MV algorithm. Results demonstrated comparable detectability performance between MV and eContrast processing, with overlapping performance metrics across all tested conditions, indicating no regression and equivalent detectability.

	- **ACR Digital Mammography Phantom Scoring**: Images of the ACR Digital Mammography phantom were reviewed and scored following ACR Quality Control Manual criteria for fibers, specks, and masses. Results met all minimum ACR scoring requirements and demonstrated equivalence between MV and predicate eContrast processing, with observed variability primarily driven by reader and dose setting rather than processing algorithm. • **Clinical Image Evaluation**: A clinical image study was conducted using previously acquired digital mammography images to assess image acceptability for screening and diagnostic use. Images were reprocessed using MV algorithm then reviewed by two MQSA qualified radiologists independently, with adjudication by a third reader if needed. Images were assessed for positioning, exposure, compression, contrast, sharpness, noise, artifacts, and overall clinical image quality. All images processed with MV were rated as acceptable for mammographic use across all evaluated attributes and evaluated processing levels. **Overall Testing Results and Conclusions** All predefined acceptance criteria were met. Bench and clinical image evaluations demonstrated that the MV image processing algorithm provides image quality performance equivalent to the predicate eContrast processing. No degradation in image quality, safety, or effectiveness was observed. **Applicability to Devices Included in the Submission** The testing described above is applicable to Senographe Pristina, SenoBright HD, Pristina Serena, and Pristina Serena Bright. The same MV 2D image processing algorithm is implemented identically across all devices included in this submission. As a result, the testing results are representative of all devices covered by this 510(k).
Conclusion:	Based on conformance to applicable standards, development under an established quality management system and design controls, and successful completion of verification, validation, bench performance testing, and clinical testing, the Senographe Pristina, SenoBright HD, Pristina Serena, and Pristina Serena Bright incorporating the MV processing are considered substantially equivalent to the predicate device with eContrast. The devices remain as safe and effective for their intended use as the predicate device.