GE Healthcare
% Barthélémy Arman
Regulatory Affairs Leader
283 rue de la Minière
BUC, 78530
FRANCE

August 6, 2021

Re: K211725
Trade/Device Name: Senographe Pristina
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: Class II
Product Code: MUE
Dated: June 4, 2021
Received: June 4, 2021

Dear Barthélémy Arman:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K211725

Device Name

Senographe Pristina

Indications for Use *(Describe)*

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.

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
PRAStaff@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 – K211725

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

Date:	August 6th, 2021
Submitter:	GE Healthcare GE Medical Systems SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE
Primary Contact Person:	Barthélémy Arman Regulatory Affairs Leader 283 rue de la Minière 78530 Buc - FRANCE Phone : +33 1 30 70 40 40 Email : Barthelemy.ARMAN1@ge.com
Secondary Contact Person:	Gregory Pessato, Regulatory Affairs Senior Manager, GE Medical Systems SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE Phone : + 33 1 30 70 93 16 Email : gregorypessato@ge.com
Device Trade Name:	**Senographe Pristina** [Design change: New version of eContrast]
Common/Usual Name:	Full Field Digital,System,X-Ray,Mammographic
Classification Names: Product Code:	21 CFR 892.1715, Class II MUE
Predicate / Reference Device(s):	Senographe Pristina (K162268) – predicate
Device Description:	eContrast is an image post-processing algorithm applied to the DICOM "for processing" images in order to generate "for presentation" images. It consists in optimizing the local contrasts while reducing the overall dynamic range. This submission is proposing a software modification consisting of a **new version of eContrast algorithm for Senographe Pristina** platform to allow more flexibility for proposing different levels

	preserving/enhancing the visibility of the different structures present in the breast image. The first version of the eContrast image processing was previously cleared for Senographe Essential platform in the 510(k)# K131885. Then it was cleared with **Senographe Pristina** platform in the 510(k) # K162268. This design change is a software and labeling only option, compatible with **Senographe Pristina** installed base and does not require any hardware modification on the Senographe Pristina platform.
Intended Use:	The **Senographe Pristina** system is intended for screening and diagnostic mammography. *Note: The intended use of Senographe Pristina cleared in K162268 is not changed.*
Indications for Use	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. *Note: The Indications for use of Senographe Pristina cleared in K162268 are not changed.*
Technology:	The modification of the eContrast post-processing algorithm is completely independent from all other parts of the digital mammographic equipment Senographe Pristina. Only the software is affected by this change. This new version of eContrast offers as before, 6 settings (eContrast 1 to eContrast 6) to accommodate different user preferences. eContrast 1 and 6 remain unchanged, with a 2-band decomposition. However, for settings 2, 3, 4 and 5, the new version of eContrast is an extension of the current algorithm with a third band decomposition to allow more flexibility for proposing different levels preserving/enhancing the visibility of the different structures present in the breast image.
Substantial Equivalence / Predicate and Reference Devices	The **new version of eContrast** algorithm for Senographe Pristina does not change the intended use and indications for use to its legally marketed predicate device, the Senographe Pristina with eContrast (K162268). The fundamental principles of operation, functionalities, specifications and technological characteristics of Senographe Pristina remain unchanged. The eContrast post-processing algorithm is modified to allow more flexibility for proposing different levels preserving/enhancing the visibility of the different structures present in the breast image. It was demonstrated in Image Quality Performance Testing that the image quality of **Senographe Pristina with this new version of**

	eContrast performs similarly as its legally marketed predicate device, the Senographe Pristina with eContrast (K162268).
Determination of Substantial Equivalence:	**Senographe Pristina with the new version of eContrast** has successfully completed required design control testing per GE Healthcare's quality management system. No unexpected test results were obtained. The design change was designed and will be manufactured under the Quality System Regulations of 21CFR 820 and ISO 13485. The following quality assurance measures were applied to the development of the system: - Risk Analysis - Design Reviews - Software Development Lifecycle - Testing on unit level (Module verification) - Integration testing (System verification) - Performance testing (Verification) - Safety testing (Verification) - Simulated use testing (Validation) The safety and performance of **Senographe Pristina with the new version of eContrast** was demonstrated through full verification testing and additional engineering bench performance testing such as: - Non-Clinical Data – Image Quality and Dose test that demonstrates that images acquired with **Senographe Pristina with the new version of eContrast** are of same quality as images acquired with Senographe Pristina with eContrast as cleared in K162268 at similar dose levels. - Clinical Data – Clinical image review by radiologists, with objective criteria defined that demonstrates the clinical image acceptability of images generated with **Senographe Pristina with the new version of eContrast.** These tests demonstrated the substantial equivalence with the predicate device and concluded that **Senographe Pristina with the new version of eContrast** do not raise any questions of safety and effectiveness.
Conclusion:	Based on: conformance to standards; development under GE Healthcare's quality management system and design controls; successful verification/validation testing and additional bench performance testing and clinical testing, GE Healthcare believes that **Senographe Pristina with the new version of eContrast** is substantially equivalent to its predicate device Senographe Pristina with eContrast as cleared in K162268. Therefore, GE concludes that Senographe Pristina remains as safe and effective for its intended use as its predicate device.