DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Ge Healthcare
Camille Vidal
Director of RA Strategy
283 Rue De La Miniere
Buc, 78530
FRANCE

September 1, 2017

Re: K163302
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: August 16, 2017
Received: August 18, 2017

Dear Camille Vidal:

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. 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.

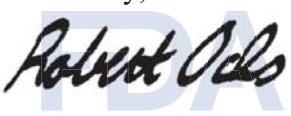
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,



Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163302

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.

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510(k) Summary

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

Date:	August 29, 2017
Submitter:	GE Healthcare Medical Systems SCS
Primary Contact Person:	Camille Vidal Director of RA Strategy GE Healthcare 283 RUE DE LA MINIERE 78530 BUC – France Phone : +1 (240) 280-5356 Email : Camille.Vidal@ge.com
Secondary Contact Person:	Diane Uriell Director of Regulatory Affairs, XR and Women's Health GE Healthcare Atlanta, GA Phone: +1 (262) 290-8212 Email: Diane.Uriell@ge.com
Device Trade Name:	Senographe Pristina
Common/Usual Name:	Full-Field Digital Mammography System
Classification Names: Product Code:	21 CFR 892.1715 – Full Field Digital Mammography System MUE
Predicate Device(s):	Senographe Pristina (K162268)
Device Description:	Patient-assisted compression (Self-Compression) is an option of the Senographe Pristina Full Field Digital Mammography system. It consists of a handheld wireless remote control to allow patient to adjust the compression force during breast positioning. The remote transmits the compression command to the Senographe Pristina. Senographe Pristina executes the command by raising or lowering the compression paddle, if conditions for motion are met.

	Patient-assisted compression is designed to minimize patients perceived pain and discomfort by giving them an active role in the application of compression. The technologist positions the patient and initiates compression. The technologist then guides the patient while she operates the remote to gradually increase compression until she reaches adequate compression.
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.
Device Comparison	The difference between Senographe Pristina (K162268) and Senographe Pristina with Patient-assisted compression (Self-Compression) is: - the addition of a wireless remote control to adjust compression during breast positioning, - the installation of a paired wireless receiver on Senographe Pristina to receive and relay the patient-assisted compression commands to the FFDM unit, Senographe Pristina includes two wired compression footswitches.
Performance Testing	The patient-assisted compression option was designed and tested in accordance with GEHC Design Controls Procedures. Verification and validation testing was performed and passed for this modification. A clinical evaluation was conducted on 30 patients undergoing standard FFDM views (CC and MLO). Image quality was assessed by MQSA qualified radiologists using the criteria set in the Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Full Field Digital Mammography System. Compared to images where compression was applied solely by the Technologist, patient-assisted compression produced images of similar quality.
Substantial Equivalence Determination	Senographe Pristina indications for use remain unchanged. New technological characteristics include a new wireless interface. Performance testing and clinical evaluation demonstrate that Senographe Pristina with patient-assisted compression (Self-Compression) is substantially equivalent to its predicate device.