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

November 3, 2016

GE Healthcare
% Mr. Gregory Pessato
Regulatory Affairs Program Manager
283 rue de la Miniere
Buc, 78530
FRANCE

Re: K162268
Trade/Device Name: Senographe Pristina
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: August 16, 2016
Received: August 17, 2016

Dear Mr. Pessato:

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 yours,

For

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)*

K162268

Device Name
Senographe Pristina

Indications for Use *(Describe)*

Senographe Pristina generates digital mammographic images that can be used for screening and in the diagnosis of breast cancer. Senographe Pristina is intended to be used in the same clinical applications as traditional mammographic screen-film systems.

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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510(k) Summary

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

Date:	August 5, 2016
Submitter:	GE Medical Systems SCS
Primary Contact Person:	Gregory Pessato Regulatory Affairs Program Manager GE Healthcare 283 RUE DE LA MINIERE 78530 BUC – FRANCE Phone : + 33 1 30 70 93 16 Email : GregoryPessato@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:	Full-field digital mammography system Class II CFR 892.1715
Product Code:	MUE
Predicate Device(s):	Senographe Essential (P990066/S021)
Device Description:	Senographe Pristina is a new Full Field Digital Mammography (FFDM) system. The system consists of an X-ray image acquisition system dedicated to breast imaging and of a control station for image acquisition, processing and display. The image acquisition system includes a Cesium Iodine digital detector, x-ray tube, integrated high voltage generator, compression paddles. The control station provides a touch-screen user interface to control image acquisition, image processing, and image transfer.
Indications for Use:	Senographe Pristina generates digital mammographic images that can be used for screening and in the diagnosis of breast cancer. Senographe Pristina is intended to be used in the same clinical applications as traditional film-based mammographic systems.

Comparison Of Technological Characteristics With The Predicate Device:	Senographe Pristina uses the same fundamental technology as Senographe Essential in terms of image acquisition (X-ray tube, detector, image processing). Senographe Pristina includes a dual track anode with silver filter, a Cesium Iodine detector Senographe Pristina was redesigned using actualized components and improved ergonomics. In particular Senographe Pristina was designed with: • Improved patient ergonomics (rounded shapes, soft armrests, thin breast support) for improved patient comfort; • Improved technologist ergonomics (large workspace, sliding implant / small breast paddle) for better access to patient and eased patient positioning; • A new gantry motorization with independent compression and X-ray tube head angulation for upgradability to 3D; • Integrated X-ray generator for reduced footprint.
Determination of Substantial Equivalence:	Senographe Pristina has the same indications for use as its predicate device. It uses the same fundamental technology as Senographe Essential. Differences between Senographe Pristina do not raise new questions of safety and effectiveness. The impact of differences between the predicate and new device has been assessed using applicable FDA Guidance and Standards. In particular the following testing was performed: • Complete Image Quality Bench Performance testing was completed showing appropriate performance. • A Clinical image evaluation was performed showing that image quality of Senographe Pristina in a clinical setting is good as assessed by expert radiologists. • Compliance was demonstrated against applicable safety and performance standards. • Successful System and Software verification and validation.
Conclusion:	Senographe Pristina is substantially equivalent to its predicate device Senographe Essential.