GE Healthcare
GE Medical Systems SCS
% Mounir Zaouali
Regulatory Affairs Leader
283 rue de la Miniere
Buc, 78530
FRANCE

October 30, 2017

Re: K172404
Trade/Device Name: SenoBright HD
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: August 4, 2017
Received: August 9, 2017

Dear Mounir Zaouali:

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 (DICE) 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 (DICE) 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,

Michael D. O'Hara 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172404

Device Name
SenoBright HD

Indications for Use *(Describe)*

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.

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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Section 5: 510(k) Summary

SenoBright HD

510(k) Summary

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

Date:	August 4, 2017
Submitter:	GE Healthcare GE Medical Systems SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE
Primary Contact Person:	Mounir Zaouali, Regulatory Affairs Leader, GE Medical Systems SCS, 283 RUE DE LA MINIERE 78530 BUC – FRANCE Phone : + 33 1 30 70 45 39 Phone : + 33 1 30 70 45 39 Fax : + 33 1 30 70 41 40 Email : Mounir.Zaouali@ge.com
Secondary Contact Person:	Diane Uriell Sr. Director of Regulatory Affairs, XR and Women's Health, GE Healthcare, Atlanta, Georgia - USA Phone +1 262 290 8212 Email: Diane.Uriell@ge.com
Device Trade Name:	SenoBright HD
Common/Usual Name:	Full Field Digital Mammography System
Classification Names: Product Code:	21 CFR 892.1715, Class II MUE
Predicate Device(s):	K103485 Contrast Enhanced Spectral Mammography (CESM)
Device Description:	The subject of this submission is a modification of Senographe Pristina FFDM system (cleared in K162268) that will introduce a new

	imaging option called SenoBright HD. This imaging option has been previously cleared for Senographe Essential FFDM system in K103485,marketed as SenoBright Contrast Enhanced Spectral Mammography (CESM). The dual energy exposures will be done following an iodine based contrast injection of the patient and with a single breast compression. The new mode of operation for Senographe Pristina system is referred to as SenoBright HD Contrast Enhanced Spectral Mammography (CESM) due to the nature of taking an exposure with the x-ray spectrum optimized for general mammographic imaging and a second exposure with the x-ray spectrum optimized for the iodine based contrast image. The main modification of the Senographe Pristina system is the addition of software feature to control the low and high energy images and post processing and recombination of those images to create FFDM like image and recombined image. These two images allow the visualization of the breast tissue in a way that is typical and familiar for mammographic imaging and the x-ray contrast enhancement in the breast at the same time.
Intended Use:	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.
Technology:	SenoBright HD and predicate device, SenoBright Contrast Enhanced Spectral Mammography (CESM), have the same intended use, same fundamental scientific technology, principle of operation and similar operating parameters.
Comparison of Technological Characteristics with The Predicate Device:	SenoBright HD The main changes between SenoBright HD and the predicate device SenoBright Contrast Enhanced Spectral Mammography (CESM) include: 1) Different hosting mammography system (Senographe Essential vs Senographe Pristina. 2) Improvements to the acquisition technique, the high energy AOP takes into account both the breast thickness and the breast density to determine the optimal X-rays techniques. This is based on the predicate and Senographe Pristina low energy AOP that takes into account both breast thickness and density.

	3) Additional artefacts management is incorporated to minimize the artefacts that may appear at the breast skin line and nipple.
Determination of Substantial Equivalence:	SenoBright HD has the same indications for use as its predicate device. It uses the same fundamental technology as Contrast Spectral Mammography (CESM). Differences between SenoBright HD 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 SenoBright HD in a clinical setting is good as assessed by expert radiologists. • Successful System and Software verification and validation.
Conclusion:	GE Healthcare considers the SenoBright HD to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).