GE Healthcare
% Florian Akpakpa
Regulatory Affairs Program Manager
283 Rue de la Minière
Buc, 78530
FRANCE

June 22, 2021

Re: K211215
Trade/Device Name: SenoBright HD
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: Class II
Product Code: MUE
Dated: April 22, 2021
Received: April 23, 2021

Dear Florian Akpakpa:

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)*

K211215

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.

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SECTION 5: 510(K) SUMMARY

NIRA FOR SENOBRIGHT HD

510(k) Number: K211215

510(k) Summary

K211215

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

Date:	June 17, 2021
Submitter:	GE Healthcare GE Medical Systems SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE
Primary Contact Person:	Florian Akpakpa Regulatory Affairs Program Manager 283 rue de la Minière 78530 Buc - FRANCE Phone : +33 1 30 70 40 40 Email : florian.akpakpa@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 40 40 Email : gregorypessato@ge.com
Device Trade Name:	SenoBright HD
Common/Usual Name:	Contrast Enhanced Spectral Mammography
Classification Names: Product Code:	21 CFR 892.1715, Class II MUE
Predicate Device:	Predicate device: SenoBright HD (K172404)
Device Description:	This submission is proposing a software update to SenoBright HD consisting of an improvement of the existing “recombination” algorithm **with the New Image Recombination Algorithm (NIRA)** by adding a local estimation of breast thickness in the images recombination to account for the non-uniformity of the breast thickness, and by compensating for potential patient movement between the 2 CESM acquisitions (Low Energy and High Energy).

	SenoBright HD (K172404) is the name of Senographe Pristina FFDM system allowing to perform Contrast Enhanced Spectral Mammography (CESM) application. The CESM acquisition technique consists in acquiring two images (one High Energy and one Low Energy) in sequence and under the same breast compression after patient injection with an iodinated contrast media. The two images are then recombined through a post-processing algorithm. This design change is a software and labeling only option, compatible with **SenoBright HD** installed base and does not require any hardware modification on the Senographe Pristina platform.
Intended Use:	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. *Note: The intended use of SenoBright HD cleared in K172404 is not changed.*
Indications for Use	Refer to Intended use.
Technology:	The update of the existing recombination algorithm to **New Image Recombination Algorithm (NIRA**) for SenoBright HD is completely independent from all other parts of the digital mammographic equipment Senographe Pristina. It therefore does not affect the dual-energy image acquisition. The changes introduced with **NIRA** are specific to the recombination algorithm and can affect exclusively the recombined image. Thus, it also does not affect the acquisition, processing and display of the low-energy image when used as a regular FFDM image. **NIRA** is an evolution of the SenoBright HD Recombination algorithm bringing the following improvements: - Use of a local estimation of breast thickness in the image recombination to account for the non-uniformity of the breast thickness. - Compensation for potential patient movement between the 2 CESM acquisitions (Low Energy and High Energy).
Substantial Equivalence / Predicate Device	The update of the existing recombination algorithm to the **New Image Recombination Algorithm (NIRA) for SenoBright HD** does not impact the intended use/indications for use of the legally marketed device SenoBright HD.

	The fundamental principles of operation, functionalities, specifications and technological characteristics of **SenoBright HD with NIRA** are identical to those of the Predicate device SenoBright HD. The image processing of SenoBright HD is improved with the New Image Recombination Algorithm by adding a local estimation of breast thickness in the images recombination to account for the non-uniformity of the breast thickness, and by compensating for potential patient movement between the 2 CESM acquisitions (LE and HE). Image Quality Performance Testing results demonstrated that the image quality of **SenoBright HD with NIRA** performs similarly as its legally marketed predicate device, SenoBright HD (K172404).
Determination of Substantial Equivalence:	**NIRA for SenoBright HD** successfully completed required design control testing per GE Healthcare's quality management system. No unexpected test results were obtained. The device is designed and will be manufactured in compliance with 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 **NIRA for SenoBright HD** was demonstrated through full verification testing and additional performance testing such as: 1. A Non-clinical Performance Testing on phantoms, including Image quality testing to demonstrate that SenoBright HD with NIRA performs at least as well as the cleared device SenoBright HD (K172404) and brings Image Quality improvements. The performance testing also demonstrates reduction of artifacts in case of either patient motion or breast thickness non-uniformity to increased lesion visibility. 2. A clinical image evaluation performed by 3 independent MQSA-qualified radiologists on 10 images with objective criteria defined. It illustrated the clinical image acceptability of images generated by **SenoBright HD with NIRA**.

	3. A clinical image evaluation comparing **SenoBright HD with NIRA** to the predicate device SenoBright HD, performed by 3 independent MQSA-qualified radiologists on 50 clinical images, showing results including: o The contrast uptake visibility assessed equivalent or better in 97% of the cases. o The visibility of artifacts assessed equivalent or lower in 99% of the cases. o The overall clinical image quality assessed superior in more than 98% of the cases. The results of verification and performance testing demonstrate the safe and effective use of **SenoBright HD with NIRA.** **SenoBright HD with NIRA** is substantially equivalent to the predicate device SenoBright HD (K172404) and there is no new question of safety and effectiveness that was raised.
Conclusion:	The fundamental principles of operation, functionalities, specifications and technological characteristics of **SenoBright HD with NIRA** are identical to those of the Predicate device SenoBright HD. Furthermore, results of successful verification activities and additional bench performance testing and clinical image evaluations do not raise any new issue regarding the safety and effectiveness of the device. Based on this information, GE Healthcare believe that **SenoBright HD with NIRA** is substantially equivalent to its predicate device SenoBright HD (K172404).