GE Healthcare
% Barthelemy Arman
Regulatory Affairs Leader
283 rue de la Miniere
78530 Buc
FRANCE

May 15, 2020

Re: K193334
Trade/Device Name: Pristina Serena Bright
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: Class II
Product Code: MUE
Dated: April 10, 2020
Received: April 17, 2020

Dear Barthelemy 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 and Part 809); 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193334

Device Name
Pristina Serena Bright

Indications for Use *(Describe)*
The Pristina Serena Bright option provides the three-dimensional location of target lesions, using information obtained from stereotactic pairs of two-dimensional X-ray images acquired with Contrast Enhanced Spectral Mammography (CESM) under the same breast compression. This information provides guidance for a variety of minimally invasive or interventional procedures in the breast such as: vacuum assisted biopsy, core biopsy, pre-surgical localization (e.g. hookwire), and fine needle aspirations (FNA).
CESM-Biopsy application is indicated for patients with suspicious lesions only seen with certainty when imaged with a contrast agent or that do not have a definite correlate on mammography or ultrasound.

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

PRISTINA SERENA BRIGHT

510(k) Summary

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

Date:	May 13th, 2020
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 Program 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:	**Pristina Serena Bright**
Common/Usual Name:	Stereotaxy biopsy guidance application using contrast imaging
Classification Names: Product Code:	21 CFR 892.1715, Class II MUE
Predicate / Reference Device(s):	Pristina Serena (K173576) – predicate / SenoBright HD (K172404) – reference
Device Description:	**Pristina Serena Bright** is a Biopsy System for Senographe Pristina. It is an additional software option that builds upon the *Pristina Serena* device (GE Healthcare Stereotaxy biopsy option for *Senographe Pristina* platform). *Pristina Serena* was cleared on May 14, 2018 (K173576).

	Pristina Serena Bright enables biopsy medical application to be done using Contrast Enhanced Spectral Mammography images. The ***Pristina Serena Bright*** add-on includes the following items: • Software: A new software version for the Senographe Pristina platform which includes software to manage the ***Pristina Serena Bright*** option. • Labeling for the CESM Biopsy Medical application. ***Pristina Serena Bright*** option is compatible with previously installed Senographe Pristina systems. ***Pristina Serena Bright*** does not require any hardware modification on the Senographe Pristina platform. The hardware that was cleared on ***Pristina Serena*** (K173576) was also not modified.
Intended Use:	**Pristina Serena Bright** is an optional accessory of Senographe Pristina intended to provide accurate location of lesions in the breast in three dimensions.
Indications for Use	The Pristina Serena Bright option provides the three-dimensional location of target lesions, using information obtained from stereotactic pairs of two-dimensional X-ray images acquired with Contrast Enhanced Spectral Mammography (CESM) under the same breast compression. This information provides guidance for a variety of minimally invasive or interventional procedures in the breast such as: vacuum assisted biopsy, core biopsy, pre-surgical localization (e.g. hookwire), and fine needle aspirations (FNA). CESM-Biopsy application is indicated for patients with suspicious lesions only seen with certainty when imaged with a contrast agent or that do not have a definite correlate on mammography or ultrasound.
Technology:	**Pristina Serena Bright** reuses the Stereotaxy principle of the cleared device Pristina Serena with Contrast Enhanced Spectral Mammography (CESM) images instead of 2D images to determine the three-dimensional (3D) location (X, Y and Z coordinates) of an object of interest in the breast (such as a suspicious lesion). With Pristina Serena Bright, the stereotaxy biopsy process uses a stereo pair of +/-15° angulated CESM X-ray images of the compressed breast. The user identifies the point of interest in each image of the stereo pair, Pristina Serena Bright computes the three dimensions coordinates (X,Y,Z) of the user-specified location in the stereo pair. The target lesion 3D coordinates information, together with the complete geometry of the device, are used to compute the required position of a biopsy device holder that will allow intervention in the

	breast at the exact target position (biopsy of sample tissue or placement of a hook wire for guidance of surgical interventions). With **Pristina Serena Bright** reuses the positioning of the biopsy device holder from Pristina Serena which is motorized and takes into account the geometry of the biopsy needles, so when the biopsy device holder is in place, the user introduces the needle in the breast until reaching the mechanical stop of the biopsy device holder. As the biopsy needle is fixed on and guided by the biopsy device holder (not handed), the needle tip (or notch) will then be at the target lesion 3D coordinates. As it was for Pristina Serena option, the **Pristina Serena Bright** allows two different needle approaches for Biopsy: vertical and horizontal (left or right). • In vertical approach, the needle is introduced from the "top" of the compressed breast. • In horizontal approach, the needle is introduced from the side of the compressed breast. Depending on patient morphology and location of the lesion to be biopsied in the breast, a radiologist might choose an approach or the other. Usually an effort is made to use an approach that would limit the distance crossed by the needle in the breast to reach the target location. **Pristina Serena Bright** option uses the Image chain of the Senographe Pristina platform with SenoBright HD (CESM application) thus the image quality of images during the biopsy procedure is equivalent to that of SenoBright HD.
Substantial Equivalence / Predicate and Reference Devices	The **Pristina Serena Bright** has identical intended use and substantially equivalent indications for use to its legally marketed predicate device, the Pristina Serena. The functionalities, specifications and technological characteristics of **Pristina Serena Bright** option are identical or equivalent to Pristina Serena. The principles of operation, image quality and dose characteristics and performances of the **Pristina Serena Bright** are equivalent to those of the reference device SenoBright HD. The **Pristina Serena Bright** was designed to provide an image quality performance equivalent to SenoBright HD and the same accuracy as Pristina Serena as demonstrated in Image Quality and Accuracy Performance Testing.

	Benefit-Risk Analysis: The proposed **Pristina Serena Bright** device offers the same benefits and risk as the predicate device Pristina Serena except for the following: • Improved benefit by allowing to perform breast biopsy for patients with suspicious findings only clearly seen when imaged with a contrast agent or that do not have a definite correlate on mammography or ultrasound, meaning potential earlier detection of breast cancer and earlier initiation of treatment. • Increased risk due to the use of contrast agent injection. The same contrast injection protocols are used in CESM and CESM-guided Biopsy, so this risk is identical to the Reference device SenoBright HD for CESM diagnostic imaging. As compared to the alternative standard of care MRI-guided Biopsy, **Pristina Serena Bright** might offer the following benefits: • From a workflow and access perspective: potential benefit with regards to reduced cost and faster access. • From a patient perspective: potentially improved patient comfort for patients with claustrophobia and allows to handle patients that cannot be imaged with MRI due to the presence of metallic objects in their body and is a shorter procedure. Regarding the other alternative to CESM-guided Biopsy, i.e. surgical biopsy, it presents a higher risk profile as it is a more invasive procedure, it has a longer recovery time and it has a higher risk of infection and bruising. Besides it might remain difficult for the surgeon to localize the appropriate area to be biopsied as no biopsy hook/wire would have been able to be placed in the breast prior to surgery. Overall GE Healthcare believes that as the increased risk is accompanied by an increase in benefit, the proposed device has a comparable benefit-risk profile to the predicate device.
Determination of Substantial Equivalence:	**Pristina Serena Bright** has successfully completed required design control testing per GE Healthcare's quality management system. No unexpected test results were obtained. This new device 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 the ***Pristina Serena Bright*** option 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 **Pristina Serena Bright** are of same quality as images acquired with Senographe Pristina with SenoBright HD at similar dose levels. - Non-Clinical Data – Biopsy accuracy testing: verification of the geometrical accuracy between the target lesion identified on the X-ray Stereo pair images and the actual position of the biopsy needle tip (or needle notch). - Non-clinical Data – Study that demonstrates the compatibility of the biopsy application on the Pristina Serena platform with the timeframe of the contrast agent visibility in the breast. These tests were performed to provide the requisite data to substantiate performance and substantial equivalence. The testing demonstrated that **Pristina Serena Bright** performs according to specifications and functions as intended.
Conclusion:	Based on: conformance to standards; development under GE Healthcare's quality management system and design controls; benefit-risk analysis, successful verification/validation testing and additional bench performance testing and clinical testing, GE Healthcare believes that the ***Pristina Serena Bright*** option is substantially equivalent to its predicate device Pristina Serena (K173576) and reference device SenoBright HD (K162268). Therefore, GE concludes that ***Pristina Serena Bright*** is as safe and effective for its intended use as its predicate device.