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

May 14, 2018

Re: K173576
Trade/Device Name: Pristina Serena
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-Field Digital Mammography System
Regulatory Class: Class II
Product Code: MUE
Dated: April 11, 2018
Received: April 13, 2018

Dear Gregory 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert A. 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)*

K173576

Device Name
Pristina Serena

Indications for Use *(Describe)*

The Pristina Serena option provides the three-dimensional location of target lesions, using information obtained from stereotactic pairs of two-dimensional X-ray images. 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).

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:	March 28, 2018
Submitter:	GE Healthcare GE Medical Systems SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE
Primary 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
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Device Trade Name:	Pristina Serena
Common/Usual Name:	Stereotaxy biopsy guidance application for a Full Field Digital Mammography System
Classification Names: Product Code:	21 CFR 892.1715, Full-field digital mammography system, Class II MUE
Predicate Device(s):	Senographe Stereo (K040125)
Reference Predicate(s)	Senographe Pristina (K162268)
Device Description:	Pristina Serena is a hardware and software add-on to the Senographe Pristina mammography platform (cleared in K162268).

	Pristina Serena uses the Stereotaxy principle to determine the three-dimensional (3D) location (X, Y and Z coordinates) of a region of interest in the breast (such as a suspicious lesion). The stereotaxy biopsy process uses a stereo pair of +/-15° angulated 2D low-dose X-ray images of the compressed breast. The user identifies the point of interest in each image of the stereo pair, Pristina Serena computes the three dimensions coordinates (X,Y,Z) of the user-specified location in the stereo pair. Pristina Serena uses the target lesion 3D coordinates and information on the geometry of the biopsy device to compute the position of a biopsy device holder that will allow intervention in the breast at the targeted position (biopsy of sample tissue or placement of a hookwire for guidance of surgical interventions). The Pristina Serena add-on includes the following items: • Hardware: ○ a Biopsy Positioner (BP) the main hardware component of the Pristina Serena option. It can be mounted on the Senographe Pristina in lieu of the Imaging Bucky. The purpose of the BP is to allows breast positioning and mechanical guidance to the target lesion for Biopsy medical application; ○ dedicated breast compression paddles for Biopsy application; ○ mechanical adaptors: pieces of hardware to allow mounting of several kind of biopsy devices on the Biopsy positioner arm. • Software: A new software version for the Senographe Pristina platform which includes software to manage the Pristina Serena option. • Labeling for the Biopsy Medical application. Pristina Serena option is compatible with previously installed Senographe Pristina systems. Pristina Serena does not require any hardware modification on the Senographe Pristina platform.
Intended Use:	Pristina Serena 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 option provides the three-dimensional location of target lesions, using information obtained from stereotactic pairs of two-dimensional X-ray images. 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).
Device Comparison:	Pristina Serena uses the same fundamental technology as Senographe Stereo in terms of lesion targeting technique (2D stereotactic biopsy), stereotactic angle, needle approach (vertical or lateral), field of view and attainable breast volume. Like its predicate, Pristina Serena supports various breast biopsy and intervention devices. The targeting accuracy of Pristina Serena is equivalent to that of Senographe Stereo. The main differences between Pristina Serena and Senographe Stereo include: - Ability to target a lesion above the compression paddle in vertical approach; - Ability to switch needle approach without patient repositioning; - A tilted needle axis to accommodate future 3D biopsy application. Pristina Serena uses the image chain of the Senographe Pristina mammography platform, therefore delivering images of quality equivalent to that of standard screening/diagnostic images.
Performance Testing	The safety and performance of the Pristina Serena option was demonstrated through engineering bench performance testing such as: • 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). • Image quality and dose performance testing to confirm that performance in Biopsy mode with Pristina Serena is substantially equivalent to that of Senographe Pristina screening/diagnostic imaging system. In addition, the device has successfully completed required design control testing per GE Healthcare's quality management system. No unexpected test results were obtained. The Pristina Serena option 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) These tests were performed to provide the requisite data to substantiate performance, claims, and ultimately substantial equivalence. Testing demonstrated that Pristina Serena performs according to specifications and functions as intended.
Substantial Equivalence Determination:	Pristina Serena has the same indications for use as its predicate Device. It uses the same fundamental technology as Senographe Stereo. Differences between Pristina Serena and Senographe Stereo do not raise new questions of safety and effectiveness. The impact of differences between the predicate and new device has been assessed using established methods. Testing including conformance to standards; successful verification/validation; and additional bench performance testing, establish that Pristina Serena is substantially equivalent to its predicate Senographe Stereo (K040125) for biopsy functions and reference predicate Senographe Pristina (K162268) for imaging performance.