



January 18, 2019

GE Healthcare  
Nicole Landreville  
Regulatory Affairs Manager  
283 rue de la Miniere BUC, 78530  
FRANCE

Re: K182951

Trade/Device Name: Pristina Serena 3D  
Regulation Number: 21 CFR 892.1715  
Regulation Name: Full-Field Digital Mammography System  
Regulatory Class: Class II  
Product Code: MUE  
Dated: October 22, 2018  
Received: October 23, 2018

Dear Nicole Landreville:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



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

## Indications for Use

510(k) Number (if known)

K182951

Device Name

Pristina Serena 3D

Indications for Use (Describe)

The Pristina Serena 3D option provides the three-dimensional location of target lesions, using information obtained from Digital Breast Tomosynthesis (DBT) 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.

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:	January 18, 2018
Submitter:	GE Healthcare GE Medical Systems SCS  283 RUE DE LA MINIERE 78530 BUC – FRANCE
Primary Contact Person:	Nicole Landreville, Eng, RAC, FRAPS Regulatory Affairs Manager 380 Hampton Heath road Burlington, ON, Canada L7L 4R2  Phone : 289-208-2365  Email : nicole.landreville@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:	<b>Pristina Serena 3D</b>
Common/Usual Name:	<ul style="list-style-type: none"><li>• Stereotaxy biopsy guidance application for a Digital Breast Tomosynthesis (DBT) Mammography System</li><li>• Biopsy System for Senographe Pristina</li></ul>
Classification Names:	21 CFR 892.1715, Class II
Product Code:	MUE

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***Pristina Serena 3D***

Predicate Device:	Pristina Serena (K173576)
Reference devices:	<ul style="list-style-type: none"> <li>• Senographe Pristina 3D (P130020/S002 and S003)</li> <li>• Hologic’s Affirm Breast Biopsy Guidance System (K122836) and Affirm Lateral Arm Upright Biopsy Accessory (K161575)</li> </ul>
Device Description:	<p><b>Pristina Serena 3D</b> is DBT Biopsy System for Senographe Pristina. It is an additional option that builds upon the <i>Pristina Serena</i> device (GE Healthcare <u>Stereotaxy</u> biopsy option for <i>Senographe Pristina</i> platform). <i>Pristina Serena</i> was cleared on May 14, 2018 (K173576).</p> <p><b>Pristina Serena 3D</b> enables biopsy medical application to be done using Digital Breast Tomosynthesis (DBT) images.</p> <p>The <b>Pristina Serena 3D</b> add-on includes the following items:</p> <ul style="list-style-type: none"> <li>• Software: A new software version for the Senographe Pristina platform which includes software to manage the <b>Pristina Serena 3D</b> option.</li> <li>• Labeling for the Biopsy DBT (3D) Medical application.</li> </ul> <p><b>Pristina Serena 3D</b> option is compatible with previously installed Senographe Pristina systems. <b>Pristina Serena 3D</b> does not require any hardware modification on the Senographe Pristina platform. The hardware that was cleared on <b>Pristina Serena 3D</b> (K173576) was also not modified.</p>
Intended Use:	<b>Pristina Serena 3D</b> is an optional accessory of Senographe Pristina intended to provide accurate location of lesions in the breast in three dimensions.
Indications for Use	The <b>Pristina Serena 3D</b> option provides the three-dimensional location of target lesions, using information obtained from Digital Breast Tomosynthesis (DBT) 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).

Technology:	<p><b>Pristina Serena 3D</b> uses the DBT 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). The X and Y coordinates are determined directly from the displayed plane as it is parallel to the detector while the Z coordinate is determined with the height of this same plane in the whole reconstructed volume.</p> <p>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 <b>Pristina Serena 3D</b>, the positioning of the biopsy device holder 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.</p> <p>As it was for Pristina Serena option, the <b>Pristina Serena 3D</b> allows two different needle approaches for Biopsy: vertical and horizontal (left or right).</p> <ul style="list-style-type: none"><li>• In vertical approach, the needle is introduced from the “top” of the compressed breast.</li><li>• In horizontal approach, the needle is introduced from the side of the compressed breast.</li></ul> <p>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.</p> <p>Since <b>Pristina Serena 3D</b> option uses the Image chain of the Senographe Pristina platform, the image quality of images during the biopsy procedure is equivalent to that of standard screening/diagnostic images of Senographe Pristina 3D.</p> <p>Regarding dose management, with <b>Pristina Serena 3D</b>, a single DBT acquisition allows for both confirming appropriate breast positioning and for lesion targeting (as opposed to a Stereotaxy procedure that requires three X-ray acquisitions: one scout image</p>
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	<p>plus a stereotaxic pair). This translates into dose reduction to patient.</p>
<p>Comparison with Reference Devices</p>	<p>In regards with Image Quality / Image processing, the Proposed device and the reference device Senographe Pristina 3D (P130020/S002 and S003) both use the same DBT image chain and DBT reconstruction.</p> <p>Regarding dose management, the Proposed <b>Pristina Serena 3D</b> uses a single AOP mode available when acquiring biopsy images. This AOP mode provides the same parameters as the Senographe Pristina 3D AOP mode called “STD+” (P130020/S003 3D STD+ on Senographe Pristina 3D submission).</p> <p>The Proposed <b>Pristina Serena 3D</b> and the reference device Hologic’s Affirm Breast Biopsy Guidance System (K122836) and Affirm Lateral Arm Upright Biopsy Accessory (K161575), both DBT features use tomosynthesis images to provide accurate location of lesions in the breast in three dimensions.</p> <p>Both 3D localization features calculate a three dimensional location for percutaneous placement for biopsy, pre-surgical localization or treatment devices.</p> <p>It is important to note also that the Senographe Pristina with Pristina Serena and <b>Pristina Serena 3D</b> offer both the 2D stereotactic or 3D tomosynthesis image acquisition.</p> <p>Both DBT features use the same method of use, they both use a Dedicated Breast Biopsy Positioner, same mechanism of action and same stated accuracy. They have the same Stereotactic Angle (<math>\pm 15^\circ</math>) but they differ slightly in DBT Tomographic angle <math>15^\circ</math> total (<math>\pm 7.5</math> degrees) for Hologics reference device versus <math>25^\circ</math> total (<math>\pm 12.5^\circ</math>) (which has no impact on the target coordinate computation for biopsy applications).</p>
<p>Determination of Substantial Equivalence:</p>	<p>The device has successfully completed required design control testing per GE Healthcare’s quality management system. No unexpected test results were obtained. The <b>Pristina Serena 3D</b> 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:</p> <ul style="list-style-type: none"> <li>• Risk Analysis</li> <li>• Design Reviews</li> </ul>

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	<ul style="list-style-type: none"> <li>• Software Development Lifecycle</li> <li>• Testing on unit level (Module verification)</li> <li>• Integration testing (System verification)</li> <li>• Performance testing (Verification)</li> <li>• Safety testing (Verification)</li> <li>• Simulated use testing (Validation)</li> </ul> <p>The safety and performance of the <b>Pristina Serena 3D</b> option was demonstrated through full verification testing and additional engineering bench performance testing such as:</p> <ul style="list-style-type: none"> <li>- Non-Clinical Data - Image Quality and Dose test that demonstrates that images acquired with <b>Pristina Serena 3D</b> are of same quality as images acquired with Senographe Pristina at similar dose levels.</li> <li>- <b>Pristina Serena 3D</b> Design and Usability Validation Report which contains evidence of validation of claims and performance bench testing</li> </ul> <p>These tests were performed to provide the requisite data to substantiate performance, claims, and ultimately substantial equivalence. The testing demonstrated that <b>Pristina Serena 3D</b> performs according to specifications and functions as intended.</p>
<p>Conclusion:</p>	<p>Based on: conformance to standards; development under GE Healthcare’s quality management system and design controls; successful verification/validation testing; utilization of the very well established stereotactic imaging principles and additional bench performance testing, GE Healthcare believes that the optional <b>Pristina Serena 3D</b> option is substantially equivalent to its predicate device Pristina Serena (K173576) and reference devices: Senographe Pristina 3D (P130020/S002 and S003) and Hologic’s Affirm Breast Biopsy Guidance System (K122836) and Affirm Lateral Arm Upright Biopsy Accessory (K161575).</p> <p>Therefore, GE Healthcare concludes that <b>Pristina Serena 3D</b> is as safe and as effective as the Predicate device for its intended use.</p>