GE Healthcare
GE Medical Systems SCS
% Nicole Landreville, P.Eng., RAC, FRAPS
Regulatory Affairs Manager
283 rue de la Miniere
78530, Buc
FRANCE

July 29, 2019

Re: K190809
Trade/Device Name: Sample Imaging for Senographe Pristina
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-Field Digital Mammography System
Regulatory Class: Class II
Product Code: MUE
Dated: June 28, 2019
Received: July 1, 2019

Dear Ms. 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 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: OMS No. 0910-0120
Expiration Date: 06/30/2020
See *PRA Statement below.*

510(k) Number *(if known)*

K190809

Device Name

Sample Imaging for Senographe Pristina

Indications for Use *(Describe)*

Sample Imaging for Senographe Pristina™ with Pristina Serena™ biopsy option is intended to provide digital X-ray images of the biopsy excised breast tissues while the patient is still under compression, to allow rapid verification that the correct tissue has been excised during the biopsy procedure.

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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Revised Section 5: 510(k) Summary

Sample Imaging for Senographe Pristina

K190809

510(k) Summary

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

Date:	July 26, 2019
510(k) Number:	K190809
Submitter:	GE Healthcare GE Medical Systems SCS 283 RUE DE LA MINIERE 78530 BUC – FRANCE
Primary Contact Person:	Nicole Landreville, P.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:	**Sample Imaging for Senographe Pristina**
Common/Usual Name:	Sample Imaging option for the Biopsy applications (Pristina Serena and Pristina Serena 3D) for the Senographe Pristina mammography platform.
Classification Names: Product Code:	21 CFR 892.1715, Class II MUE
Predicate Device:	MAMMOMAT Revelation with InSpect feature (K173408)
Reference devices:	Pristina Serena (K173576)
Device Description:	***Sample Imaging for Senographe Pristina*** is an additional option that builds upon the Pristina Serena Stereotaxy biopsy device cleared on May 14, 2018 (K173576).

	The ***Sample Imaging*** option enables the imaging of breast tissue samples collected during biopsy medical application. In other words, the **Sample Imaging** option provides the capability to image, within the same examination, and while the patient is still under compression, the breast tissue samples collected during biopsy procedures performed with any biopsy medical application available on the system. The acquisition of such images is done with dose to the patient limited to scatter radiation from the samples.
Intended Use:	The ***Sample Imaging*** option is intended to provide digital X-ray images of biopsy excised breast tissues.
Indications for Use	The ***Sample Imaging*** option for Senographe Pristina™ with Pristina Serena™ biopsy option is intended to provide digital X-ray images of the biopsy excised breast tissues while the patient is still under compression, to allow rapid verification that the correct tissue has been excised during the biopsy procedure.
Technology:	The ***Sample Imaging*** option uses an angulated 2D view acquired either at +15° or -15° gantry angulation to image breast tissue samples collected during biopsy procedures performed during biopsy procedures with any biopsy medical application available on the system. The angulated image is acquired without moving the patient from the position in which the sample collection was performed, nor modifying the compression applied to the breast. Therefore, sample imaging does not affect the biopsy setup. The ***Sample Imaging*** option can be used to image breast tissues extracted during micro or macro biopsy with a vacuum assisted device or core biopsy device for histopathology analysis.
Substantial Equivalence / Predicate and Reference Devices	The proposed device **Sample Imaging** for Senographe Pristina™ and the predicate device InSpect feature on the Mammomat Revelation (K173408) share an equivalent intended use and indications for use and are used for the purpose of providing digital X-Ray images of biopsy excised breast tissues. Both features provide the capability of continuous zoom which allows the user to reach a zoom identical or better that what the magnification glass offers. The fundamental principles of operation, functionalities, specifications and technological characteristics of ***Sample Imaging*** option are equivalent to InSpect feature on the MAMMOMAT Revelation. The proposed device ***Sample Imaging*** for Senographe Pristina™ and the reference device Pristina Serena™ offer the same image chain but different image processing are applied.

	The ***Sample Imaging*** function was designed to provide an image quality performance equivalent or better than Pristina Serena™ as demonstrated in Image Quality Performance Bench Testing results. The image quality and dose characteristics and performances of the ***Sample Imaging*** are equivalent to those of the reference device Pristina Serena™.
Determination of Substantial Equivalence:	The device has successfully completed required design control testing per GE Healthcare's quality management system. No unexpected test results were obtained. The ***Sample Imaging for Senographe Pristina*** 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) The safety and performance of the ***Sample Imaging*** option was demonstrated through full verification testing and additional engineering bench performance testing such as: - Non-Clinical Data: o Image Quality test that demonstrates that images acquired with ***Sample Imaging*** are of same quality as images acquired with Pristina Serena or Pristina Serena 3D. The image quality assessment conducted shows that ***Sample Imaging*** views have better performance than 2D scout biopsy and DBT biopsy views. The image quality assessment was performed with the ACR mini stereotactic breast biopsy accreditation phantom. The test results demonstrate that image quality of ***Sample Imaging*** mode is sufficient to verify the presence of targeted tissues in the samples and to achieve its indications for use.

	o MTF was measured using the same acquisition techniques and compared between biopsy area and sample imaging area. Images were processed with "FineView" adapted to biopsy and simple imaging parameters respectively. With "FineView" applied, the MTF of the Sample images is higher than the MTF for the Biopsy 2D images at any frequency. o Patient Radiation Dose Testing: Since the breast of the patient is not in the primary X-ray beam, no direct radiation dose is delivered to the patient. However, since the primary X-Ray beam can be in close proximity to the breast, scatter radiation from the samples and detector were measured. The Air Kerma at the point of skin entry in the patient's breast closest to the biopsy samples being imaged was measured at 1.99% of the Entrance Skin Air Kerma (ESAK) from a biopsy AOP scout view for an average breast. - ***Sample Imaging*** Design and Usability Validation Report contains evidence of validation of claims and performance bench testing. These tests were performed to provide the requisite data to substantiate performance, claims, and ultimately substantial equivalence. The testing demonstrated that ***Sample Imaging for Senographe Pristina*** 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; successful verification/validation testing; utilization of the very well established stereotactic imaging principles and additional bench performance testing, GE Healthcare believes that the optional ***Sample Imaging for Senographe Pristina*** is substantially equivalent to its predicate device MAMMOMAT Revelation with InSpect feature (K173408) and reference device Pristina Serena (K173576). Therefore, GE Healthcare concludes that ***Sample Imaging for Senographe Pristina*** is as safe and as effective as the Predicate device for its intended use.