Siemens Medical Solutions USA, Inc.
℅ Martin Rajchel
Sr. Manager, Regulatory Affairs
40 Liberty Boulevard
MALVERN PA 19355

November 12. 2021

Re: K212621
Trade/Device Name: MAMMOVISTA B.smart
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 17, 2021
Received: August 18, 2021

Dear Martin Rajchel:

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K212621

Device Name

MAMMOVISTA B.smart

Indications for Use *(Describe)*

MAMMOVISTA B.smart is a dedicated softcopy review environment for both screening and diagnostic mammography as well as digital breast tomosynthesis. Its user interface and workflow have been optimized to support experienced mammography and tomosynthesis reviewers in both screening and diagnostic reading. Efficiency and reading quality are supported by various specialized features. MAMMOVISTA B.smart provides visualization and image enhancement tools to aid a qualified radiologist in the review of digital mammography and digital breast tomosynthesis datasets, as well as other modalities of breast images.

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: MAMMOVISTA B.smart

K212621

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65 – 1A
Malvern, PA 19355

Date Prepared: August 18, 2021

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

1. General Information:

Importer / Distributor:
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355
Establishment Registration Number: 2240869

Location of Manufacturing Site:
Siemens Healthcare GmbH
Siemensstr. 1
91301 Forchheim, Germany
Establishment Registration Number: 3004977335

2. Contact Person:

Martin Rajchel
Sr. Manager, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
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Alternate Contact Person:

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Malvern, PA 19355, USA
adams.denise@siemens-healthineers.com

3. Device Name and Classification :

Trade Name:	MAMMOVISTA B.smart
Classification Name:	Medical Image Management and Processing System
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.2050
Device Class:	II
Product Codes:	LLZ

4. Legally Marketed Predicate Device:

Trade Name:	*syngo*.Breast Care
510(k) Number:	K123420 (Cleared February 1, 2013)
Classification Name:	Picture Archiving and Communications System
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.2050
Device Class:	II
Product Codes:	LLZ

5. Device Description:

MAMMOVISTA B.smart is an optional software application for the Siemens Healthineers *syngo*.via platform (K191040). MAMMOVISTA B.smart is an image viewing and processing software environment dedicated to breast image display. It is designed to provide the performance required for the high data volume of digital tomosynthesis and the display of multi-modality breast images, such as those from MRI and ultrasound. Individual workflows can be adapted for either screening or diagnostic purposes.
MAMMOVISTA B.smart runs on a PC and can be used for Mammography image review together with monitors cleared for Mammography diagnostics. The software solution provides for the display of DICOM compatible information, such as breast density and CAD (Computer Aided Diagnostics) markers.

6. Indication for Use:

MAMMOVISTA B.smart is a dedicated softcopy review environment for both screening and diagnostic mammography as well as digital breast tomosynthesis. Its user interface and workflow have been optimized to support experienced mammography and tomosynthesis reviewers in both screening and diagnostic reading. Efficiency and reading quality are supported by various specialized features. MAMMOVISTA B.smart provides visualization and image enhancement tools to aid a qualified radiologist in the review of digital mammography and digital breast tomosynthesis datasets, as well as other modalities of breast images.

7. Substantial Equivalence:

The MAMMOVISTA B.smart software device is substantially equivalent to the commercially available *syngo.*Breast Care (K123420, cleared February 1, 2013).

The device remains within the same classification regulation for the same technology as the predicate device. The new software design was completed in accordance with Quality Management System Design Controls comparable to the processes available for the predicate device. The scope of internationally recognized standards compliance was updated to the standards recognized at the time of the design of the new software.

8. Summary of Technological Characteristics of the Subject Device Compared with the Predicate Device:

MAMMOVISTA B.smart has a similar indications for use as the predicate *syngo*.Breast Care. MAMMOVISTA B.smart is a software-only solution that runs on a compatible client server environment together with monitor displays cleared for Mammography.

Optional software packages provide for the specific customer needs such as the display of tomosynthesis datasets with tomosynthesis specific layouts and tools.

The following table compares the main performance data of the subject device with the predicate device.

Comparison of the Subject Device (MAMMOVISTA B.smart) to Predicate Device (*syngo*.Breast Care)

Feature	**Subject device**	**Predicate device (K123420)**	**Comment**
Regulation Description	System, image processing, radiological	System, image processing, radiological	N/A
Device Name	**MAMMOVISTA B.smart**	***syngo*.Breast Care**	N/A
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	N/A
Classification Product Code	LLZ	LLZ	N/A
Indications for use	MAMMOVISTA B.smart is a dedicated softcopy review environment for both screening and diagnostic mammography as well as digital breast tomosynthesis. Its user interface and workflow have been optimized to support experienced mammography and tomosynthesis reviewers in both screening and diagnostic reading. Efficiency and reading quality are supported by various specialized features. MAMMOVISTA B.smart provides visualization and image enhancement tools	*syngo*.Breast Care is a dedicated softcopy review environment for both screening and diagnostic Mammography as well as digital breast tomosynthesis. Its user interface and workflow have been optimized to support experienced mammography and tomosynthesis reviewers in both screening and diagnostic reading. Efficiency and reading quality are supported by various specialized features. *syngo*.Breast Care provides visualization and image enhancement tools to aid a	Subject device Indications for Use includes multi-modality images (e.g., MRI and ultrasound)

	to aid a qualified radiologist in the review of digital mammography and digital breast tomosynthesis datasets, as well as other modalities of breast images.	qualified radiologist in the review of digital mammography images and digital breast tomosynthesis datasets. The radiologist is responsible for making the diagnosis of the images presented	
Architecture	Client / server environment	Client / server environment	N/A
Display of 3rd party Computer Aided Diagnostics (CAD) markers	Yes	Yes	N/A
Display and processing of DBT images	Yes	Yes	N/A
DICOM 3.0	Same	Same	N/A
DICOM compatible modalities	MG (Digital Mammography X-Ray) MG Tomo (Mammography Tomosynthesis images) MR (Magnetic Resonance) US (Ultrasound)	MG (Digital Mammography X-Ray) MG Tomo (Mammography Tomosynthesis images) MR (Magnetic Resonance) US (Ultrasound)	N/A
Display of breast density values	Yes	Yes	N/A

9. Summary of Non-Clinical Tests:

Non-clinical tests were conducted for the MAMMOVISTA B.smart software during product development. The MAMMOVISTA B.smart software conforms to the following voluntary standards:

Standards Reference Number and Date	Title of Standard
IEC 62366-1 2015 Ed 1.0	Medical devices – Application of usability engineering to medical devices

ISO 14971: 2019	Medical devices – application of risk management to medical devices
IEC 62304 2015, Ed.1.1	Medical device software - Software life cycle processes
NEMA PS 3.1 - 3.20 2016	Digital Imaging and Communications in Medicine (DICOM) Set
IEC 82304-1: 2016	Health software – Part 1: General requirements for product safety

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued on May 11, 2005, is also included as part of this submission. Non-clinical tests (integration and functional) were conducted on the MAMMOVISTA B.smart during product development. The risk analysis was completed and risk controls were implemented to mitigate identified hazards. The test results support that all the software specifications have met the acceptance criteria. Verification and validation testing were found acceptable to support the claim of substantial equivalence.

Siemens did not conduct any clinical tests for the subject device.

10. General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling and the information provided will enable the user to operate the device in a safe and effective manner. Several safety features including visual and audible warnings are incorporated into the system design.

Risk management is ensured via a hazard analysis which is used to identify potential hazards. These potential hazards are controlled via software development, verification, and validation testing. Furthermore, the operators are qualified healthcare professionals familiar with and responsible for the review of digital mammography images and digital breast tomosynthesis datasets.

11. Conclusion as to Substantial Equivalence:

The MAMMOVISTA B.smart' s Indication for Use is similar to that of the predicate device. The Indications for Use statement has been revised for clarity and includes multi-modality image reading (e.g., MRI and ultrasound) and does not impact the intended use. The operating environment and software design are similar. Image display devices (monitors) with the same or similar specifications will be used to display the mammography images.

Verification and validation testing demonstrate that the MAMMOVISTA B.smart performs as intended. The non-clinical test data demonstrate that the MAMMOVISTA B.smart device performance is comparable to the predicate device that is currently marketed for the same intended use.

It is Siemens' opinion that the MAMMOVISTA B.smart does not introduce any new potential safety risks and is substantially equivalent to the *syngo.*Breast Care.

12. Guidance documents

The following FDA guidance documents were utilized in this Premarket Notification:

Content of Premarket Submission for Management of Cybersecurity in Medical Devices - Guidance for Industry and Food and Drug Administration Staff
Document Issued on October 2, 2014

Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Document issued on May 11, 2005

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices - Guidance for Industry and Food and Drug Administration Staff
Document issued on September 14, 2018.

The 510(k) Program: Evaluation Substantial Equivalent in Premarket Notifications 510(k) - Guidance for Industry and Food and Drug Administration Staff
Document issued on July 28, 2014

Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
Document issued on: May 11, 2005