March 27, 2024

Siemens Medical Solutions USA, Inc.
Denise Adams
Regulatory Affairs Professional
40 Liberty Boulevard
MALVERN, PA 19355

Re: K233539
Trade/Device Name: MAMMOMAT B.brilliant
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-Field Digital Mammography System
Regulatory Class: Class II
Product Code: MUE
Dated: February 23, 2024
Received: February 23, 2024

Dear Denise Adams:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming

product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233539

Device Name

MAMMOMAT B.brilliant

Indications for Use *(Describe)*

The digital mammography system MAMMOMAT B.brilliant is intended to be used for mammography exams, screening, diagnosis, biopsies and dual energy procedures under the supervision of medical professionals. Mammography images can be interpreted by either hard copy film or soft copy workstation.

With Biopsy Option: The InSpect feature for MAMMOMAT B.brilliant with HD Biopsy options is intended to provide digital X-ray images of core biopsy specimens in order to allow rapid verification that the correct tissue has been excised with 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary: MAMMOMAT B.brilliant (K233539)

Company: Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355

Date Prepared: March 27, 2024

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:

Denise Adams, RAC
Regulatory Affairs Professional
Siemens Medical Solutions USA, Inc.
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adams.denise@siemens-healthineers.com

Alternate Contact Person:

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Malvern, PA 19355, USA
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3. Device Name and Classification:

Trade Name:	MAMMOMAT B.brilliant
Classification Name:	Full Field Digital, System, X-Ray Mammographic
Classification Panel:	Radiology
Classification Regulation:	21 CFR § 892.1715
Device Class:	II
Product Code:	MUE

4. Legally Marketed Predicate Device

Trade Name:	MAMMOMAT Revelation
510(k) #:	K193166
Classification Name:	Full Field Digital, System, X-Ray Mammographic
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1715
Device Class:	II
Product Code:	MUE

5. Device Description:

MAMMOMAT B.brilliant is a floor-mounted, full field digital mammography system for screening, diagnostic, and biopsy procedures on standing, seated, or recumbent patients.

The system consists of an examination stand with x-ray generator, a gantry with tube housing assembly, and mammography support table, including detector and an acquisition workstation with a radiation shield. The MAMMOMAT B.brilliant comes with a variety of compression plates and a biopsy attachment for diagnostic adjunct procedures.

The MAMMOMAT B.brilliant features an updated detector, a new image acquisition chain (tube, filter, collimator) and improvements to the image acquisition workflow and biopsy workflow. Adaptations have been made to the image processing due to the new image acquisition hardware and the Soft- and hardware feature improvements. Patient positioning features like a head rest have been added.

6. Indications for Use:

The digital mammography system MAMMOMAT B.brilliant is intended to be used for mammography exams, screening, diagnosis, biopsies and dual energy procedures under the supervision of medical professionals. The Mammography images can be interpreted by either hard copy film or soft copy workstation.

With Biopsy Option: The InSpect feature for MAMMOMAT B.brilliant with HD Biopsy options is intended to provide digital X-ray images of core biopsy specimens in order to allow rapid verification that the correct tissue has been excised with the biopsy procedure.

7. Substantial Equivalence:

The Siemens MAMMOMAT B.brilliant with VA10 is substantially equivalent to the commercially available Siemens MAMMOMAT Revelation with VC20 (K193166).

Table 1: Comparison of the Subject to the Primary Predicate

Attributes	Predicate device MAMMOMAT Revelation VC20, K193166	Subject device MAMMOMAT B.brilliant	Remarks
Indications for Use	The MAMMOMAT Revelation is intended to be	The digital mammography system MAMMOMAT	Same

Attributes	Predicate device MAMMOMAT Revelation VC20, K193166	Subject device MAMMOMAT B.brilliant	Remarks
	used for mammography exams, screening, diagnostics, biopsies and dual energy procedures under the supervision of medical professionals. The Mammography images can be interpreted by either hard copy film or soft copy workstation. With Biopsy Option: The InSpect feature for MAMMOMAT Revelation with HD Biopsy options is intended to provide digital X-ray images of core biopsy specimens in order to allow rapid verification that the correct tissue has been excised with the biopsy procedure.	B.brilliant is intended to be used for mammography exams, screening, diagnosis, biopsies, and dual energy procedures under the supervision of medical professionals. Mammography images can be interpreted by either hard copy film or soft copy workstation. With Biopsy Option: The InSpect feature for MAMMOMAT B.brilliant with HD Biopsy options is intended to provide digital X-ray images of core biopsy specimens in order to allow rapid verification that the correct tissue has been excised with the biopsy procedure.	
Product Code	MUE	MUE	Same
System configuration			
X-ray Stand	Floor mounted X-ray system	Floor mounted X-ray system	Different; housing design changed; new Collision detection zone; fixed head rest and ComfortGuide Display added to support patient

Attributes	Predicate device MAMMOMAT Revelation VC20, K193166	Subject device MAMMOMAT B.brilliant	Remarks
			positioning and technologist
X-ray Generator kV range	5 kW 23 kV to 35 kV 45 kV to 49 kV	5 kW 23 kV to 40 kV 45 kV to 49 kV	Different; Increased kV range for FFDM
X-ray Tube	P49	STTA _P49_FFS	Different; increased x-ray output
Anode-filter combinations	W / Rh (50 µm), W/Ti (1.0 mm)	W / Al (1.0 mm) W / Ti (1.3 mm) W/Al (0.7 mm)	Different; Thickness and material changed.
Collimator	Automatic for all sizes	Automatic for all sizes	Different; more compact: Gain more space below collimator e.g. for Biopsy
Compression unit	Automatic and manual operation	Automatic and manual operation	Different; Redesign for better access to emergency release
Object table	Carbon fiber mammography support system	Carbon fiber mammography support system	Minor; Lower contour adapted; same material, same supplier
Detector	LMAM2v2	LMAM3-DS85	Minor; new generation of detector; same supplier, same technology;
Detector software	PEGASUS	PEGASUS	Minor; new SW Revision
Detector manufacturer	Analogic Canada	Analogic Canada	Same
Detector TFT	Amorphous Silicon (a-Si)	Amorphous Silicon (a-Si)	Same
Detector size	24 cm x 30 cm	24 cm x 30 cm	Same
Array size	2816 x 3584	2816 x 3584	Same
Pixel size	85 µm x 85 µm	85 µm x 85 µm	Same
Grid	Reciprocating 5:1 ratio	Reciprocating 5:1 ratio	Same
Magnification table	Magnification 1.5 and 1.8	Magnification 1.5 and 1.8	Minor; Lower contour adapted; same material

Attributes	Predicate device MAMMOMAT Revelation VC20, K193166	Subject device MAMMOMAT B.brilliant	Remarks
Biopsy attachment	Yes	Yes	Minor; Design change and Lower contour adapted; same material
Tomo-guided biopsy	Yes	Yes	Different; lateral biopsy optional with tomo pre- and postfire;
Monitor/ Display	19” and 21” TFT display	19” and 21” TFT display	Same
Software controlled functions			
System software	VC20	VA10	Different; Improved functionality
TiCEM	Dual energy imaging W/Ti 1,0 mm HE	Dual energy imaging W/Ti 1,3 mm HE	Different; Algorithm is the same; Parameters adapted due to x-ray spectra; increased tmean energy of the X-ray spectrum
AEC Calculation	AEC calculation	AEC calculation	Different; Algorithm is the same. AEC parameters adjusted due to x-ray spectra. AEC pre-shot acquired for Tomo biopsy adapted
Operating System	Windows 10	Windows 10	Same
Image processing algorithms	Opview	Opview	Different; Same algorithms; different implementation (now on GPU) to accelerate process; state of the art on GPU as higher performance. Parameter adjustments due to new tube /x-ray spectra
DICOM	Yes	Yes	Same

Attributes	Predicate device MAMMOMAT Revelation VC20, K193166	Subject device MAMMOMAT B.brilliant	Remarks
Anti Scatter Grid	Yes	Yes	Same
Headrest Face shield	Face shield mounted on tube head	Separate stationary head rest with optional face shield	Different; New to support patient positioning; Face shield material is identical.
PRIME	yes	yes	Different; Functionality same; adjustments due to new filter; Application range reduced.
other			
Accessories	Compression plate holders	Compression plate holders	Different for Biopsy and magnification; Adapted as travel path distance for compression unit is changed; other holders are the same
Accessories	Compression plates	Compression plates	same

8. Summary of Technological Characteristics of the Subject Device as compared with the Predicate Devices:

The MAMMOMAT B.brilliant is based on the same principle of operation. It features an updated detector, a new image acquisition chain (tube, filter, collimator) and improvements to the image acquisition workflow and biopsy workflow. The image processing algorithms for FFDM are identical to those of the predicate with parameter adjustments due to the new image acquisition chain.

The subject device does introduce improvements to the present features. These improvements are:

- New software version
- Improvements to the positioning of patients with ComfortMove functionality
- Improvements to the Biopsy workflow
- Improvements to the Contrast Enhanced Mammography

In addition, hardware changes are made compared to MAMMOMAT Revelation

- New generation of detector
- New tube with flying focal spot

- New and changed filter materials
- New AWS-PC with state-of-the art performance
- Improved comfort for patient due new positioning support
- Improvements concerning usability like a ComfortGuide Display and the adapted lighting concept.

9. Summary of Non-Clinical Tests:

The Siemens MAMMOMAT B.brilliant was tested and complies with the voluntary standards listed in the table below:

Table 2: List of Standards

DICOM standard	Digital Imaging and Communications in Medicine Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management (ISO 12052); English version EN ISO 12052 / NEMA PSE3
IEC 60601-1:2005 + A1:2012 Edition 3.1 + ANSI/AAMI ES 60601-1 /AMENDMENT 1: 2012 C1:2009/(R)2012 + A2:2010/(R)2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014 Edition 4.0	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances - Requirements and tests / Endorsement notice (EN 60601-1-2 Edition 4.0 / IEC 60601-1-2:2014)
IEC 60601-1-3: 2008 + A1: 2013	Medical electrical equipment – Part 1: General requirements for safety – 3rd collateral standard: General requirements for radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008)
IEC 60601-1-6 Edition 3.2 2020-07	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability (IEC 60601-1-2:2013)
IEC 60601-2-28:2017 Edition 3.0	Medical electrical equipment Part 2-28: Particular requirements for the basic safety and essential performance of Xray tube assemblies for medical diagnosis (IEC 60601-2-28:2017)

IEC 60601-2-45:2011+A1:2015 Ed 3.1	Medical electrical equipment Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices (IEC 60601-2-45:2011 + A1:2015)
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 14971:2019	Medical devices – Application of risk management to medical devices
IEC 60825-1:2014	Safety of laser products - Part 1: Equipment classification and requirements
IEC 62304:2006 + A1:2015 Edition 1.1	Medical device software - Software life cycle processes
IEC 62366-1 Edition 1.1 2020-06	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices

In addition, the following tests were conducted:

Table 3: Summary oof non-clinical Tests

Test	Objective	Test Method	Acceptance Criteria	Results
Detector characteristics	Ensure non-inferiority to predicate	As described in FDA's *Class II Special Controls Guidance Document: Full-Field Digital Mammography System*	Same or better than predicate	passed
Dual energy imaging	Ensure non-inferiority to predicate	Performance tests	Same or better than predicate	passed
Targeting accuracy	Ensure accuracy of the biopsy device	Accuracy tests with phantom and calibration needle.	The needle tip must be no more than +/-1 mm in x, y, z	passed

			direction from the selected target point.	
Biopsy images	Ensure non-inferiority to predicate	Performance tests	Same or better than predicate	passed
PRIME	Ensure non-inferiority to predicate	Performance tests	Same or better than predicate	passed

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirement Specification Reviews
- Design Reviews
- Integration testing (System verification)

The data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests (integration and functional) were conducted on the MAMMOMAT B.brilliant 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.

10. Summary of Clinical Tests:

Siemens conducted a clinical image evaluation to determine if the FFDM images, when reviewed by expert radiologists, are of acceptable quality for mammographic usage. The image evaluation was carried out according to FDA's *Class II Special Controls Guidance Document: Full-Field Digital Mammography System.* The image sets consisted of 19 FFDM cases including 4 cases with biopsy, 2 with PRIME, 3 with contrast enhanced mammography cases (TiCEM), 3 of those cases with magnification views.

The radiologists found all image sets to be of acceptable overall clinical image quality. The clinical image evaluation performed by 3 expert readers, together with the non-clinical testing conducted to support the change, demonstrates that the image quality of the MAMMOMAT B.brilliant with VA10 is substantially equivalent to the predicate device, the MAMMOMAT Revelation with VC20. The clinical image evaluation showed that the new MAMMOMAT B.brilliant system generates high quality images.

In summary, this clinical image evaluation, serving as supporting evidence, together with the non-clinical testing, has met the objective in demonstrating substantial equivalence when comparing the Siemens MAMMOMAT B.brilliant with VA10 to the Siemens MAMMOMAT Revelation with VC20.

11. 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.

In addition, the MAMMOMAT B.brilliant is continuously monitored and if an error occurs the system functions will be blocked and an error message will be displayed.

Furthermore, the operators are health care professionals familiar with and responsible for the x-ray examinations to be performed. To minimize electrical, mechanical, and radiation hazards, Siemens adheres to recognized and established industry practice and all equipment is subject to final performance testing.

12. Conclusion as to Substantial Equivalence:

The MAMMOMAT B.brilliant with VA10 has the same intended use, fundamental scientific technology, and performance characteristics as the predicate, MAMMOMAT Revelation with VC20 (K193166). Therefore, the MAMMOMAT B.brilliant with VA10 is substantially equivalent to the predicate MAMMOMAT Revelation with VC20.

13. Guidance documents

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

- *Electromagnetic Compatibility (EMC) of Medical Devices*
  Guidance for Industry and Food and Drug Administration Staff
  Document issued on June 6, 2022.

- *Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Full-Field Digital Mammography System*
  Document issued on March 27, 2012

- *Guidance for Industry and FDA Staff - Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*
  Document issued on June 14, 2023

- *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

- *Electronic Submission Template for Medical Device 510(k) Submissions*
  Guidance for Industry and Food and Drug Administration Staff
  Document issued October 2, 2023

- *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance for Industry and Food and Drug Administration Staff*
  Document issued on September 27, 2023.