June 18, 2026

Siemens Medical Solutions USA, Inc.
Denise Adams
Regulatory Affairs Professional
40 Liberty Bouldevard
Malvern, Pennsylvania 19355

Re: K253678
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: May 19, 2026
Received: May 20, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Digitally signed by Michael D. O'hara -S
Date: 2026.06.18 13:44:47 -04'00'

For

Yanna Kang, 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.

510(k) Number *(if known)*
K253678

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: MAMMOMAT B.brilliant VA11 (K253678)

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

Date Prepared: June 17, 2026

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:
Martin Rajchel
Sr. Manager, Regulatory Affairs
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard
Malvern, PA 19355, USA
martin.rajchel@siemens-healthineers.com

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 B.brilliant
510(k) #:	K233539
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 VA11 features updates to the Contrast Enhanced Mammography (CEM) functionality including a new optional workflow step for a CEM biopsy scout.

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 VA11 is substantially equivalent to the commercially available Siemens MAMMOMAT B.brilliant with VA10 (K233539).

Table 1: Comparison of the Subject to the Primary Predicate

Attributes	predicate device MAMMOMAT B.brilliant VA10	Subject device MAMMOMAT B.brilliant VA11	Remarks
Indication 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. 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.	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.	Same
Product Code	MUE	MUE	Same

Attributes	predicate device MAMMOMAT B.brilliant VA10	Subject device MAMMOMAT B.brilliant VA11	Remarks
X-ray Stand	Floor mounted X-ray system	Floor mounted X-ray system	Same
X-ray Generator kV range	5 kW 23 kV to 40 kV 45 kV to 49 kV	5 kW 23 kV to 40 kV 45 kV to 49 kV	Same
X-ray Tube	STTA _P49_FFS	STTA _P49_FFS	Same
Anode-filter combinations	W / Al (1.0 mm) W / Ti (1.3 mm) W/Al (0.7 mm)	W / Al (1.0 mm) W / Ti (1.3 mm) W/Al (0.7 mm)	Same
Collimator	Automatic for all sizes	Automatic for all sizes	Same
Compression unit	Automatic and manual operation	Automatic and manual operation	Same
Object table	Carbon fiber mammography support system	Carbon fiber mammography support system	Same
Detector	LMAM3-DS85	LMAM3-DS85	Same
Detector software	PEGASUS	PEGASUS	Same
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	Same
Biopsy attachment	Yes	Yes	Same
(tomo-guided /stereotactic) Biopsy	Yes	Yes	Different; Additional optional contrast enhanced biopsy scout (ClearCEM scout)
Monitor/ Display	19” and 21” TFT display	19” and 21” TFT display	Same
Anti Scatter Grid	Yes	Yes	Same
Headrest Face shield	Separate stationary head rest with optional face shield	Separate stationary head rest with optional face shield	Same

Attributes	predicate device MAMMOMAT B.brilliant VA10	Subject device MAMMOMAT B.brilliant VA11	Remarks
System software	VA10	VA11	Different; Improved functionality
TiCEM /ClearCEM	Dual energy imaging	Dual energy imaging	Different; Algorithm is adapted
AEC Calculation	AEC calculation	AEC calculation	Same
Operating System	Windows 10	Windows 10	Same
Image processing algorithms	Opview	Opview	Same
DICOM	Yes	Yes	Same
PRIME	yes	yes	Same
Accessories	List of compatible components in the operator manual	List of compatible components in the operator manual	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. The image processing algorithms for FFDM are identical to those of the predicate.

The subject device does introduce improvements. These improvements are:

- Improvements to Contrast Enhanced Mammography
- New optional workflow step for CEM biopsy scout

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 Edition 2.2 2021-01 CONSOLIDATED VERSION	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
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 14971:2019	Medical devices – Application of risk management to medical devices
IEC 60825-1 Edition 2.0 2007-03	Safety of laser products - Part 1: Equipment classification and requirements
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes
IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION	Medical devices - Part 1: Application of usability engineering to medical devices
ISO 17664-2 First edition 2021-02	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 of non-clinical Tests

Test	Objective	Test Method	Acceptance Criteria	Results
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 direction from the selected target point.	Passed
Biopsy images	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 the contrast enhanced images reviewed by expert radiologists are of acceptable quality for mammographic usage. The evaluation of six 4-view-ClearCEM cases and four ClearCEM biopsy scout cases by five expert radiologists and additional 3 4-view-ClearCEM cases have been evaluated by four expert radiologists. It was conducted to demonstrate that ClearCEM and ClearCEM biopsy scout images are of acceptable clinical image quality.

The clinical cases were acquired on the MAMMOMAT B.brilliant system using VA11 acquisition software and standard of practice care during screening and diagnostic mammography. Each ClearCEM case consisted of four image pairs (low energy image and recombined iodine image (Insight CEM)): craniocaudal (CC) and mediolateral oblique (MLO) views of each breast and represented a spectrum of fatty and dense breasts. Each ClearCEM biopsy scout case consisted of at least one scout image pair (low energy image and recombined iodine image).

For ClearCEM all five radiologists found all image sets to be of “good” or better overall clinical image quality. Except for reader 2 who score the overall image quality of all 6 cases as “good” the other 4 readers scored all cases with “very good” or “excellent.

For ClearCEM Scout all five radiologists found all image sets to be of “good” or better overall clinical image quality except for reader 2 who scored the overall image quality for cases 3 and 4 with “satisfactory”. Cases 3 and 4 were scored with “good” by two radiologists, with “very good” by one radiologist and with “excellent” by another radiologist.

The additional image evaluation of the 3 cases demonstrates the ability of Siemens’ new ClearCEM algorithm to downgrade the BI-RADS category of lesions for certain images when no lesion enhancement is seen, but BPE might be present.

The contrast enhanced image quality of the MAMMOMAT B.brilliant with VA11 is substantially equivalent to the predicate device, the MAMMOMAT B.brilliant VA10. The clinical image evaluation showed that the MAMMOMAT B.brilliant VA11 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 VA11 to the MAMMOMAT B.brilliant with VA10.

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 VA11 has the same intended use, fundamental scientific technology, and performance characteristics as the predicate, MAMMOMAT B,brilliant VA10 (K233539). Therefore, the MAMMOMAT B.brilliant with VA11 is substantially equivalent to the predicate MAMMOMAT B.brilliant with VA10.

13. Guidance documents

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

- *Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff*
  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 Equivalence 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 June 27, 2025.