Siemens Medical Solutions USA, Inc.
% Mr. Martin Rajchel
Sr. Regulatory Affairs Specialist
40 Liberty Boulevard, 65-1A
MALVERN PA 19355

June 12, 2020

Re: K193166
Trade/Device Name: MAMMOMAT Revelation
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: Class II
Product Code: MUE
Dated: May 15, 2020
Received: May 18, 2020

Dear Mr. 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); 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193166

Device Name
MAMMOMAT Revelation

Indications for Use *(Describe)*

The MAMMOMAT Revelation is intended to be 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.

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 Revelation-K193166

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

Date Prepared: May 13, 2020

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 Systems USA, Inc.
40 Liberty Boulevard, 65-1A
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
Regulatory Affairs Specialist
Siemens Medical Solutions USA, Inc.
40 Liberty Boulevard, 65-1A
Malvern, PA 19355, US

3. Device Name and Classification:

Trade Name:	MAMMOMAT Revelation
Classification Name:	Full Field Digital, System, X-Ray Mammographic
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1715
Device Class:	2
Product Code:	MUE

4. Legally Marketed Predicate Device

Trade Name:	MAMMOMAT Revelation
510(k) #:	K173408
Classification Name:	Full Field Digital, System, X-Ray Mammographic
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1715
Device Class:	2
Product Code:	MUE

5. Device Description:

MAMMOMAT Revelation 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 Revelation comes with a variety of compression plates and a biopsy attachment for diagnostic adjunct procedures.

The MAMMOMAT Revelation features an updated system software to VC20, including new detector software for faster system calibration, and improvements to the contrast enhanced mammography feature and biopsy workflow. Improvements include adjustments to the image processing for contrast enhanced mammography to present a more homogeneous image. The biopsy attachment was complemented with a spacer plate to be used for easier access to the biopsy region.

6. Indication for Use:

The MAMMOMAT Revelation is intended to be 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.

7. Substantial Equivalence:

The Siemens MAMMOMAT Revelation with VC20 is substantially equivalent to the commercially available Siemens MAMMOMAT Revelation with VC10 (K173408).

Table 1: Comparison of the Subject to the Primary Predicate

Attributes	Subject device MAMMOMAT Revelation VC20	Predicate device MAMMOMAT Revelation VC10, K173408	Remarks
Indication for Use	The MAMMOMAT Revelation is intended to be 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	The MAMMOMAT Revelation is intended to be 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	Same

Attributes	Subject device MAMMOMAT Revelation VC20	Predicate device MAMMOMAT Revelation VC10, K173408	Remarks
	rapid verification that the correct tissue has been excised with the biopsy procedure.	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	Same
X-ray Generator kV range	5 kW 23kV to 49kV	5 kW 23kV to 49kV	Same
X-ray Tube	Same tube	Same tube	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	LMAM2v2	LMAM2v2	Same
Detector software	PEGASUS	MOSAIC	Improved detector handling
Detector manufacturer	Anrad	Anrad	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
tomosynthesis guided biopsy	Yes	Yes	Same
Monitor/ Display	19” and 21” TFT display	19” and 21” TFT display	Same
Software controlled functions			
System software	VC20	VC10	Improved functionality
TiCEM	Dual energy imaging	Dual energy imaging	Improved image processing
AEC Calculation	AEC calculation is done in the acquisition workstation	AEC calculation is done in the acquisition workstation	Same
Operating System	Windows 10	Windows 10	Same
Image processing algorithms	Opview	Opview	Same
DICOM	Yes	Yes	Same

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

The MAMMOMAT Revelation is based on the same mechanical stand as the predicate device. X-ray generation and control are also the same. The collimator, compression unit, and AEC technology are the same. The image processing algorithms for FFDM are identical to those of the predicate. There are no new features but improvements to the detector handling, biopsy workflow, and dual energy image processing.

9. Summary of Non-Clinical Tests:

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

Table 2: Non-clinical performance testing

Reference Number, Date and Title of Standard
IEC 60601-1: 2012, Ed 3.1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: Ed 4, 2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-3 Ed 2.1, 2013, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-2-28 Ed 2.0, 2010, Medical electrical equipment - Part 2: Particular requirements for the safety and essential performance of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
IEC 60601-2-45: 2015, 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 62366: 2015, Ed 1.0 Medical devices - Application of usability engineering to medical devices
ISO 14971:2007, Medical devices - application of risk management to medical devices
IEC 62304: 2015–06 Edition 1.1,, Medical device software - Software life cycle processes
ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
NEMA PS 3.1 - 3.20: 2016, Digital Imaging and Communications in Medicine (DICOM) Set
IEC 60336: 2005, Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots

In addition, the following tests were conducted:

Table 3: Summary of 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 diagnostic image quality	Images have been evaluated by Radiologists	Image quality equivalent to images acquired with VC10	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.	Within 1 mm of target
Biopsy procedure with spacer plate	Ensure safety and effectiveness of biopsy	Workflow tests with and without spacer plate	Same results with and without spacer plate	Passed
Cleaning of the spacer plate	Ensure effectiveness of cleaning procedure	Cleaning and disinfection validation	According to AAMI TIR 30 and AAMI ST58	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)

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 the *Class II Special Controls Guidance Document: Full-Field Digital Mammography System.* The image sets consisted of 8 FFDM cases including one case with diagnostic images; three DBT biopsy cases with the new spacer plate; and 4 contrast enhanced mammography cases. It was determined that the images from the subject device are substantially equivalent to those from the predicate device.

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 Revelation 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 Revelation with VC20 has the same intended use, fundamental scientific technology, and performance characteristics as the predicate, MAMMOMAT

Revelation with VC10 (K173408). Therefore, the MAMMOMAT Revelation with VC20 is substantially equivalent to the predicate MAMMOMAT Revelation with VC20.

13. 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

- *Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices - Guidance for Industry and Food and Drug Administration Staff*
  Document issued on July 11, 2016

- *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 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: Evaluating Substantial Equivalence in Premarket Notifications - Guidance for Industry and Food and Drug Administration Staff*
  Document issued on July 28, 2014