Siemens Medical Solutions USA, Inc.
% Ms. Denise Adams
Regulatory Affairs Specialist
40 Liberty Boulevard, 65-1A
MALVERN PA 19355

March 21, 2018

Re: K173408
Trade/Device Name: MAMMOMAT Revelation
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: February 19, 2018
Received: February 20, 2018

Dear Ms. 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 (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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K173408

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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K173408
510(k) Summary: MAMMOMAT Revelation

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

Date Prepared: February 16, 2018

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
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
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Alternate Contact Person
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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 Devices**

Primary predicate:
Trade Name: MAMMOMAT Inspiration Prime
510(k) #: K123520
Classification Name: Full Field Digital, System, X-Ray Mammographic
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1715
Device Class: Class II
Product Code: MUE

Secondary predicates:

Trade Name: AFFIRM BREAST BIOPSY GUIDANCE SYSTEM
510(k) #: K122836
Classification Name: System, X-ray, Mammographic
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1710
Device Class: Class II
Product Code: IZH

Trade Name: CONTRAST ENHANCED DIGITAL MAMMOGRAPHY
510(k) #: K123873
Classification Name: Full Field Digital, System, X-Ray Mammographic
Classification Panel: Radiology
Classification Regulation: 21 CFR §892.1715
Device Class: Class II
Product Code: MUE

Recalls: There are no recalls for these predicate devices.

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 detector (LMAM 2v2), an upgrade to the MS Windows 10 operating system, the capability to do contrast enhanced mammography and tomosynthesis guided biopsy.

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 is substantially equivalent to the commercially available Siemens MAMMOMAT Inspiration PRIME (primary predicate) (K123520), the Hologic Contrast Enhanced Digital Mammography (secondary predicate) (K123873) and the Hologic Affirm Breast Biopsy Guidance System (secondary predicate) (K122836).

Table 1: Comparison of the Subject to the Primary Predicate

Attributes	Subject device MAMMOMAT Revelation	Primary Predicate MAMMOMAT Inspiration PRIME K123520	Remarks
Intended 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.	The MAMMOMAT Inspiration system is intended for mammography exams, screening, diagnosis, and stereotactic biopsies under the supervision of medical professionals. Mammographic images can be interpreted by either hard copy film or soft copy workstation.	Same but biopsy term more general and dual energy added
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 35kV	kV range increased for CEDEM
X-ray Tube	Same tube but shielding of THA improved for higher kV	Same tube	No Mo focus

Attributes	Subject device MAMMOMAT Revelation	Primary Predicate MAMMOMAT Inspiration PRIME K123520	Remarks
	and the Molybdenum focus is not being used anymore		anymore
Beam Limiting Device	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	LMAM2	Improved readout electronics
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 3585	2816 x 3585	Same
Pixel size	85 µm x 85 µm	85 µm x 85 µm	Same
Grid	Reciprocating 5:1 ratio	Reciprocating 5:1 ratio	Same
PRIME	Same as in K123520	Cleared with K123520	Same
Magnification table	Magnification 1.5 and 1.8	Magnification 1.5 and 1.8	Same
Biopsy attachment	Yes	Yes	Improved
Monitor/ Display	19” and 21” TFT display	19” and 21” TFT display	Same
Software controlled functions			
AEC Calculation	AEC calculation is done in the acquisition workstation	AEC calculation is done in the acquisition workstation	Same
Operating System	Windows 10	Windows XP	upgraded
Image processing algorithms	Opview	Opview	Same
DICOM	Yes	Yes	Same

Table 2: Comparison of the Subject to the Secondary Predicate for tomosynthesis guided biopsy

Attributes	Subject device MAMMOMAT Revelation	Secondary predicate Hologic, Affirm Breast Biopsy Guidance System, K122836	Remarks
Biopsy			
Intended 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.	The Affirm Breast Biopsy Guidance System is an optional accessory for the Selenia Dimensions Mammography System. It is designed to allow the accurate localization of lesions in the breast in three dimensions. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).	Both include biopsy With specimen imaging added to subject device
Product Code	MUE	IZH	Both contain accessories for mammography
Hardware	Biopsy unit slides onto object table	Biopsy unit slides onto object table	Same
Patient positioning	Stereotactic biopsy can be performed on seated and recumbent patients	Stereotactic biopsy can be performed on seated and recumbent patients	Same
Accuracy	+/-1 mm in X, Y and Z axis	+/-1 mm in X, Y and Z axis	Same
Biopsy volume (vertical needle guidance)	50 mm x 40 mm x 110 mm (2“ x 1.6“ x 4.3“)	50 mm x 40 mm x 110 mm (2“ x 1.6“ x 4.3“)	Same
Biopsy	50 mm x 40 mm x 60 mm (2“	50 mm x 40 mm x 60 mm (2“ x	Same

Attributes	Subject device MAMMOMAT Revelation	Secondary predicate Hologic, Affirm Breast Biopsy Guidance System, K122836	Remarks
volume (lateral needle guidance)	x 1.6“ x 2.4“)	1.6“ x 2.4“)	
Tube swivel range in stereo mode	– 15° and + 15°	– 15° and + 15°	Same
Biopsy compression plate with window	96 mm x 100 mm (3.8“ x 3.9“) (window size 52 mm x 42 mm (2“ x 1.7“), vertical needle guidance	96 mm x 100 mm (3.8“ x 3.9“) (window size 52 mm x 42 mm (2“ x 1.7“), vertical needle guidance	Same
Biopsy compression plate without window	96 mm x 100 mm (3.8“ x 3.9“) (lateral needle guidance)	96 mm x 100 mm (3.8“ x 3.9“) (lateral needle guidance)	Same
Software controlled functions for stereotactic biopsy			
Workflow	Automated workflow	Automated workflow	Same

Table 3: Comparison of the Subject to the Secondary Predicate for Contrast Enhanced Dual Energy Mammography (CEDEM):

Attributes	Subject device MAMMOMAT Revelation with CEDEM option	Secondary predicate Hologic, Contrast Enhanced Digital Mammography K123873	Remarks
Intended 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.	Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the Selenia Dimension system. The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an *adjunct* following mammography and/or ultrasound exams to localize a known or suspected lesion.	Both include dual energy
Product Code	MUE	MUE	Same
High energy image			
kV range	45kV to 49kV	45kV to 49kV	Same
Processing	Weighted subtraction	Weighted subtraction	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 primary device. X-ray generation and control are the same. The Collimator, Compression unit and AEC technology are the same. The image processing algorithms are identical to those of the primary predicate. The novel features Contrast Enhanced Mammography and tomosynthesis guided biopsy are similar to the technology used with the secondary predicates from Hologic.

9. Summary of Non-Clinical Tests:

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

Table 4: Conformance to Standards

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, 2012 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: 2014, Ed 1.1 Medical devices - Application of usability engineering to medical devices
ISO 14971:2007, Medical devices - application of risk management to medical devices
IEC 62304: 2006, 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

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In addition, the following bench tests were also conducted:

Table 5: Summary of Bench Tests

Test	Objective	Test Method	Acceptance Criteria	Results
Detector characteristics	Ensure non-inferiority to predicate	As described by FFDM special control guidance	Same or better than predicate	passed
Dual energy imaging	Ensure diagnostic image quality	As described in System Test Record Dual Energy – Appendix E	As described in System Test Record Dual Energy	passed
Targeting accuracy	Ensure accuracy of the biopsy device	Accuracy tests with phantom and calibration needle. System Test Record Dual Energy appendix E	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

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. 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 continually is 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.

11. Conclusion as to Substantial Equivalence:

The MAMMOMAT Revelation has the same intended use, fundamental scientific technology and performance characteristics as the predicate devices. Therefore the MAMMOMAT Revelation is substantially equivalent to the primary predicates the MAMMOMAT Inspiration PRIME and the secondary predicates from Hologic, Affirm Breast Biopsy Guidance System and Contrast Enhanced Digital Mammography.