DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 10, 2017

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

Re: K163252
Trade/Device Name: Mammomat Fusion with Stereotactic Biopsy
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: November 17, 2016
Received: November 18, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163252

Device Name
Mammomat Fusion with Stereotactic Biopsy

Indications for Use *(Describe)*

The Mammomat Fusion system generates digital mammographic images that can be used for screening, diagnosis and stereotactic biopsies of the breast under supervision of medical professionals. The Mammomat Fusion system is intended to be used in the same clinical applications as traditional film-screen mammography systems. The Mammomat Fusion system may also be used for additional diagnostic workup of the breast.

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.

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510(k) Summary: Mammomat Fusion with Stereotactic Biopsy

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

Date Prepared: January 10, 2017

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

   Manufacturing Site:
   Siemens Healthcare GmbH
   Siemensstr. 1
   91301 Forchheim Germany

   Establishment Registration Number:
   3004977335

2. **Contact:**
   Siemens Medical Solutions USA, Inc.
   Denise Adams, RAC
   Regulatory Affairs Specialist
   40 Liberty Boulevard
   Mail Code: 65-1A
   Malvern, PA 19355-9998, USA
   Phone: +1.610.448.6139
   Mobile: +1.610.944.4686
   adams.denise@siemens.com

3. **Device Name and Classification:**

Trade Name:	Mammomat Fusion with Stereotactic Biopsy
Device:	Full Field Digital Mammographic X-Ray system
Reg. Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	MUE

Submission Type:	Traditional 510(k)
Regulation Number:	21 CFR 892.1715
Device Class:	2

4. **Legally Marketed Predicate Devices:**

Primary predicate	
Trade Name:	Mammomat Inspiration
Device:	Full Field Digital Mammographic X-Ray system
Reg. Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	MUE
Submission Type:	510(k) (K122286, 02/22/2013)
Regulation Number:	21 CFR 892.1715
Device Class:	2

Reference predicate	
Trade Name:	Mammomat Fusion
Device:	Full Field Digital Mammographic X-Ray system
Reg. Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	MUE
Submission Type:	510(k) (K151645, 09/14/2015)
Regulation Number:	21 CFR 892.1715
Device Class:	2

5. **Device Description:**

Mammomat Fusion is a floor-mounted full field digital mammography system for screening and diagnostic procedures on standing, seated or recumbent patients.

The stereotactic biopsy accessory uses a computer and imaging performed in at least two planes to localize a target lesion (such as a tumor or micro calcifications in the breast) in three-dimensional space and guide the removal of tissue for examination by a pathologist under a microscope.

The biopsy is attached to the Mammomat Fusion examination stand and comprises a control panel for automatic motorized movement of the needle holder to the pre-set position. There are special biopsy compression plates as well as a face shield to protect the patient from movements of the swivel arm.

The display and control of the biopsy unit are performed via the workstation. Biopsy examinations can be executed with vertical and horizontal needle guidance. For stereo exposures the swivel arm of the Mammomat Fusion is tilted ± 15° to both sides.

6. Indication for Use:

The Mammomat Fusion system generates digital mammographic images that can be used for screening, diagnosis and stereotactic biopsies of the breast under supervision of medical professionals. The Mammomat Fusion system is intended to be used in the same clinical applications as traditional film-screen mammography systems. The Mammomat Fusion system may also be used for additional diagnostic workup of the breast.

7. Substantial Equivalence:

The Siemens Mammomat Fusion with Stereotactic Biopsy is substantially equivalent to the commercially available Siemens Mammomat Inspiration (primary predicate) (K122286) and Mammomat Fusion (reference predicate) (K151645).

The Mammomat Fusion with Stereotactic Biopsy is the same system as the reference predicate the Mammomat Fusion with the exception of the biopsy feature. The stereotactic biopsy accessory is identical to the stereotactic biopsy accessory used with the primary predicate the Mammomat Inspiration.

Table 1: Comparison of the Subject to the Primary Predicate

Attributes	**Subject device Mammomat Fusion with Stereotactic Biopsy**	**Primary predicate K122286 Mammomat Inspiration**	**Remarks**
Stereotactic Biopsy Option			
Indications for Use	The Mammomat Fusion system generates digital mammographic images that can be used for screening and diagnosis, **and stereotactic biopsies** of the breast under supervision of medical professionals. The Mammomat Fusion system is intended to be used in the same clinical applications as traditional film-screen mammography systems. The Mammomat Fusion system may also be used for additional diagnostic workup of the breast.	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 for biopsy
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 volume	50 mm x 40 mm x 60 mm (2“ x	50 mm x 40 mm x 60 mm (2“ x	**Same**

Attributes	Subject device Mammomat Fusion with Stereotactic Biopsy	Primary predicate K122286 Mammomat Inspiration	Remarks
(lateral needle guidance)	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**
Image processing	OpView, the image impression for biopsy images and screening/diagnostic images is identical	OpView, the image impression for biopsy images and screening/diagnostic images is identical	**Same**

Table 2: Comparison of the Subject to the Reference Predicate

Attributes	Subject device Mammomat Fusion with Stereotactic Biopsy	Reference predicate K151645 Mammomat Fusion	Remarks
Indications for use	The Mammomat Fusion system generates digital mammographic images that can be used for screening and diagnosis, and stereotactic biopsies of the breast under supervision of medical professionals. The Mammomat Fusion system is intended to be used in the same clinical applications as traditional film-screen mammography systems. The Mammomat Fusion system may also be used for additional diagnostic workup of the breast.	The Mammomat Fusion system generates digital mammographic images that can be used for screening and diagnosis of the breast under supervision of medical professionals. The Mammomat Fusion system is intended to be used in the same clinical applications as traditional film-screen mammography systems. The Mammomat Fusion system may also be used for additional diagnostic workup of the breast.	Same except for biopsy
System configuration			
X-ray Stand	Floor mounted X-ray system	Floor mounted X-ray system	**Same**
X-ray Generator	5 kW 30kV, 1s	5 kW 30kV, 1s	**Same**
X-ray Tube	Same tube but only Tungsten is used	Same tube but only Tungsten is used	**Same**

Attributes	Subject device Mammomat Fusion with Stereotactic Biopsy	Reference predicate K151645 Mammomat Fusion	Remarks
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**
Grid	Reciprocating 5:1 ratio	Reciprocating 5:1 ratio	**Same**
Magnification table	Magnification 1.5 and 1.8	Magnification 1.5	Adding 1.8 table
Biopsy unit	Yes	No	Reason for 510(k)
Power requirements	208V, 220V, 230V, 240V, 277V, ± 10%, single-phase 208V, 220V, 230V, 240V, 277V, ± 10%, two-phase, 50/60 Hz	208V, 220V, 230V, 240V, 277V, ± 10%, single-phase 208V, 220V, 230V, 240V, 277V, ± 10%, two-phase, 50/60 Hz	**Same**
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**
Detector Controller Software	detector controller software for PaxScan 3023M detector	detector controller software for PaxScan 3023M detector	**Same**
Operating System	Windows 7	Windows 7	**Same**
Network Interfaces DICOM Send	Yes	Yes	**Same**
DICOM Print	Yes	Yes	**Same**
DICOM Query / Retrieve	Yes	Yes	**Same**
DICOM Get work list / MPPS	Yes	Yes	**Same**
DICOM Dose Structured Report	Yes	Yes	**Same**
Detector			
Detector manufacturer	Varian	Varian	**Same**
Detector TFT	Cesium Iodide (Csl) and amorphous Silicon (a-Si)	Cesium Iodide (Csl) and amorphous Silicon (a-Si)	**Same**
Detector size	23 cm x 30 cm	23 cm x 30 cm	**Same**

Attributes	Subject device Mammomat Fusion with Stereotactic Biopsy	Reference predicate K151645 Mammomat Fusion	Remarks
Array size	2790 x 3580	2790 x 3580	**Same**
Pixel size	83 µm x 83 µm	83 µm x 83 µm	**Same**

The Mammomat Fusion with Stereotactic Biopsy has the same intended use, fundamental scientific technology and performance characteristics as the predicates. Documentation is provided to support a claim of substantial equivalence to Siemens' predicate devices the Mammomat Inspiration and the Mammomat Fusion (K122286 and K151645).

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

Mammomat Fusion with Stereotactic Biopsy is based on the same mechanical stand as the primary. 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 predicates. Mammomat Fusion with Stereotactic Biopsy will now feature the same biopsy accessory as the primary predicate Mammomat Inspiration.

9. Summary of Non-Clinical Tests:

The Siemens Mammomat Fusion with Stereotactic Biopsy was tested and complies with the voluntary standards listed in the table below:

Table 3: Conformance to Standards

Reference Number, Date and Title of Standard
AAMI ANSI, ES 60601-1: 2005 /(R) 2012, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2007, 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 2008 + A1: 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 62366: 2007, Medical devices - Application of usability engineering to medical devices
ISO 14971:2012, 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
IEC 60601-2-28: 2010, Medical electrical equipment - Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis - Ed. 1.0
IEC 61223-3-2:2007, Evaluation and routine testing in medical imaging departments -

Reference Number, Date and Title of Standard
Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment
IEC 60601-2-45: 2011, Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices
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 bench tests were also conducted and passed:

Table 4: Summary of Bench Tests

Test	Objective	Test Method	Acceptance Criteria	Results
Targeting accuracy	Ensure accuracy of the biopsy device	Remove plastic tray, attach phantom and compress manually. Take a scout exposure and a stereo pair and check reference points. Set an accurate target mark then select needle. Select target mark with corresponding needle and needle holder. Transmit the target mark to the biopsy unit. Mount the calibration needle and check the needle tip position of the 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 needle	Correct biopsy needle will be used	Position biopsy phantom on object table and compress. Acquire scout and check that target for biopsy is within the possible biopsy volume. Acquire stereo pair and check and adapt reference marks if applicable. Set target in both stereo images and select calibration needle. Check that target coordinates and calculated distance between needle tip and biopsy table are displayed. Set further target at the border of the biopsy volume. Select a needle that won't reach the target.	A message will appear that the target cannot be reached with this needle and an appropriate needle length is suggested.	The message was received that the target could not be reached with that needle and an appropriate needle length was suggested.

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

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

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 Fusion with Stereotactic Biopsy is continually 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.

10. Conclusion as to Substantial Equivalence:

The Mammomat Fusion with Stereotactic Biopsy has the same intended use, fundamental scientific technology and performance characteristics as the predicate devices. Therefore the Mammomat Fusion with Stereotactic Biopsy is substantially equivalent to the primary predicate the Mammomat Inspiration and the reference predicate the Mammomat Fusion.