DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.
% Mr. Darren Dorman
Regulatory Affairs Specialist III
51 Valley Stream Parkway
MALVERN PA 19355

September 14, 2015

Re: K151645
Trade/Device Name: Mammomat Fusion
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: June 17, 2015
Received: June 18, 2015

Dear Mr. Dorman:

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,

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)*

K151645

Device Name
Mammomat Fusion

Indications for Use *(Describe)*

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.

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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SIEMENS Healthcare

510(k) Summary: Mammomat Fusion

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

Date Prepared: June 17, 2015

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:
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Establishment Registration Number:
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2. Contact Person:

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3. Device Name and Classification:

Trade Name:	Mammomat Fusion
Device:	Full Field Digital Mammographic X-Ray system
Regulation 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
Regulation 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
Recall Information:	There have been no recalls for this device

Secondary predicate:

Trade Name:	GE Senographe DS
Device:	Full Field Digital Mammographic X-Ray system
Regulation Medical Specialty:	Radiology
Review Panel:	Radiology
Product Code:	MUE
Submission Type:	PMA (P990066, S019 05/25/2005).
Regulation Number:	21 CFR 892.1715
Device Class:	2
Recall Information:	Recall No. Z-1044-2011 Recall No. Z-0115-2012

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 system consists of an examination stand with integrated microprocessor-controlled high-voltage generator as well as an optional radiation shield with a height-adjustable control desk with an integrated Acquisition Workstation (AWS). The moveable swivel arm on the examination stand contains the X-ray tube on the top end and the object table with the detector on the bottom end. The detector is a full field digital mammography detector.

6. Indication for Use:

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.

7. Substantial Equivalence:

The Siemens Mammomat Fusion is substantially equivalent to the commercially available Siemens Mammomat Inspiration (Primary predicate) and the GE Senographe DS (Secondary predicate).

Predicate Device Name and Manufacturer	510(k) / PMA Number	Clearance / Approval Date	Comparable properties
Primary: Mammomat Inspiration, Siemens Medical Solutions USA, Inc.	K122286	02/22/2013	- (FFDM) - Mechanical design - Software - Image processing algorithms
Secondary Senographe DS, GE Healthcare	P990066, S019	05/25/2005	- FFDM - Detector characteristics

X-ray generation and control used with the Mammomat Fusion is identical to the Mammomat Inspiration. The Detector technology has been changed from a Selenium to a Cesium Iodide Thin film transistor (TFT). Updated software controls the system. Image processing algorithms are unchanged from the predicate Mammomat Inspiration. The Acquisition Workstation (AWS) is identical. The Mammomat Fusion does not feature the stereotactic biopsy option.

The performance data of the Mammomat Fusion are compared to the GE Senographe DS as the have same physical detector characteristics.

The subject device - the Mammomat Fusion system is within the same classification regulation for a similar intended use as the modified Mammomat Inspiration system, the primary predicate device. The subject device has the same fundamental scientific technology as the primary predicate device. The subject device has the same or better performance data as the secondary predicate. Documentation is provided to support a claim of substantial equivalence to Siemens' predicate device the Mammomat Inspiration (K122286, 02/22/2013) and to the GE Senographe DS (P990066, S019 05/25/2005).

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

Mammomat Fusion is based on the same mechanical stand as the primary predicate – MAMMOMAT Inspiration system. 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. Mammomat Fusion does not feature the biopsy option. Similar tests and the same scope of voluntary standards have been applied to the Mammomat Fusion as compared to the primary predicate, the Mammomat Inspiration.

The detector technology has been changed to Cesium Iodide technology. The performance of the detector has been compared to the secondary predicate the GE Senographe DS and the results of the non-clinical tests provide evidence of substantial equivalence to the secondary predicate.

9. Summary of Non-Clinical Tests:

The Siemens Mammomat Fusion complies with the voluntary standards as listed in the following table:

Reference Number, Date and Title of Standard
AAMI ANSI 60601-1: 2005, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
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, 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

Reference Number, Date and Title of Standard
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
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 - 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: 2011, 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

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

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

Clinical and Non-clinical testing was conducted in accordance with the "Guidance for industry and FDA Staff: Class II Special Control Guidance Document: Full-Field digital Mammography System," (issued on March 27, 2012) and "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" (issued August 6, 1999). All test results were satisfactory.

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 Fusion 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.

11. Conclusion as to Substantial Equivalence:

The Mammomat Fusion is intended for similar indications for use as the predicate FFDM systems. The system design (Mammography stand, X-ray generator, tube, collimator and image processing algorithms) are similar, if not the same, as with the primary predicate, Mammomat Inspiration. Detector material and performance are compared to the secondary predicate system the GE Senographe DS. Siemens considers the Mammomat Fusion to be substantially equivalent to the predicate devices - Mammomat Inspiration and GE Senographe DS.