FEB 2 2 2013

510(k) Summary: Mammomat Inspiration

Company: Siemens Medical Systems, Inc.
51 Valley Stream Parkway
Malvern, PA 19355

Date Prepared: July 27, 2012

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, Inc.
51 Valley Stream Parkway
Malvern, PA 19355
Establishment Registration Number:
2240869

Manufacturing Site:
SIEMENS AG Sector Healthcare
Henkestraße 127
91050 Erlangen
Establishment Registration Number:
8010024

2. Contact Person:

Ms. Patricia D. Jones
Technical Specialist, Regulatory Submissions
Siemens Medical Solutions USA, Inc.
51 Valley Stream Parkway D-02
Malvern, PA 19355
Phone: (610) 448 -3536 Fax: (610) 448-1787
Email: patricia.d.jones@siemens.com

3. Device Name and Classification:

Trade Name:	Mammomat Inspiration
Device:	Full Field Digital, system, X-Ray Mammographic
Regulation:	Medical Specialty Radiology
Review Panel	Radiology
Product Code	MUE

Submission Type	510(k)
Regulation Number	892.1715
Device Class	2

4. Legally Marketed Predicate Device

Trade Name:	Mammomat Inspiration
Device:	Full Field Digital, system, X-Ray Mammographic
Regulation:	Medical Specialty Radiology
Review Panel	Radiology
Product Code	MUE
Submission Type	PMA Supplement
Regulation Number	892.1715
Device Class	3

5. Device Description:

Mammomat Inspiration is a floor-mounted mammography system for screening, diagnostic and biopsy procedures on standing, seated or recumbent patients.

The system consists of an examination stand with integrated, microprocessor-controlled, high-frequency generator as well as a radiation shield with an optional height-adjustable control desk in which the Acquisition Workstation (AWS) can be integrated. A swivel arm contains the X-ray tube on the top end and the object table with the detector on the bottom end.

The Mammomat Inspiration was submitted as a supplement (S006) to PMA P030010. This supplement was approved on November 05, 2010. All Full Field Digital Mammography (FFDM) systems were reclassified to class 2 and currently require a 510(k) submission.

6. Indication for Use:

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.

7. Substantial Equivalence:

The Siemens Mammomat Inspiration with VB30 is substantially equivalent to the commercially available Siemens Mammomat Inspiration with VB10. The Mammomat Inspiration was described

as a supplement (S006) to PMA P030010. This supplement was approved on November 05, 2010. All Full Field

X-ray generation and control used with the Mammomat Inspiration VB30 is identical to the Mammomat Inspiration with VB10. Detector TFT specifications, image processing algorithms remain unchanged. The Acquisition Workstation (AWS) is identical.

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

Mammomat Inspiration with VB30 features the same functionality as the predicate Mammomat Inspiration with VB10 and in addition a feature called "Automatic Quality Control". "Automatic Quality Control" will assist the user in the quality tests required according to 21 CFR 900. "Automatic Quality Control" is an optional feature. VB30 also improves some workflow functions. The portfolio of accessories has been extended to include more options for biopsy systems to compliment the needs of the Mammography suite.

9. 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 Inspiration 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 Inspiration VB30 is intended for the same indications for use as the predicate Mammomat Inspiration VB10. The imaging properties (TFT with pixel size and number and image processing algorithms) have not been modified. It is Siemens opinion, that the Mammomat Inspiration VB30 is substantially equivalent to the Mammomat Inspiration VB10.

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

February 22, 2013

Patricia D. Jones
Siemens Medical Solutions, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K122286
Trade/Device Name: Mammomat Inspiration
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: February 11, 2013
Received: February 12, 2013

Dear Ms. Jones:

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.

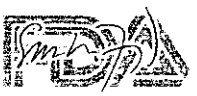
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K122286

Device Name: Mammomat Inspiration

Indications for Use:

The Mammomat Inspiration system is intended for mammography exams, screening, diagnosis, and stereotactic biopsies under supervision of medical professionals.

Mammographic images can be interpreted by either hardcopy film or softcopy workstation.

Prescription Use __Yes___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of *In Vitro* Diagnostic and Radiological Health

510(k) K122286