SIEMENS SEP 3 1996 K963093

510 (k) SUMMARY

I. **GENERAL INFORMATION:**

Establishment:

•Address: Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ. 08830

•Registration Number: 2240869

•Contact Person: Kathleen Rutherford
Manager, Regulatory Submissions
Telephone: (908) 321- 4779
TELEFAX: (908) 321 - 4841

Date of Summary Preparation:

Device Name:

•Trade Name: Siremobil Compact

•Common Name: Mobile X-ray System

•Classification Name: Mobile X-ray System

•Classification: Class II

Performance Standards: 21 CFR, Subchapter J

All system components to which the above standard applies are certified to conform with 21 CFR subchapter J

II. **SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION.**

Device Description:

The Siremobil Compact is a mobile x-ray C-ram which consists of a high frequency generator, X-ray tube assembly, image intensifier, TV camera, film cassette attachment, Laser light localizers, electronics cabinet and a monitor trolley which consists of the digital memory device, image monitor(s), and user interface. The Siremobil Compact is designed to meet the space and clinical requirements of the clinical environments identified below.

Siemens Medical Systems, Inc.

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The Siremobil Compact is designed for easy maneuverability, durability and high efficiency and performance. The system operation is designed to provide the user with an ergonomic clinically optimized interface. The Siremobil Compact can operate in three modes, Fluoroscopy with Last Image Hold, Pulsed Fluoroscopy with Last Image Hold and Digital Radiography. The user can process the images utilizing such techniques as recursive filtration, summation or spatial noise suppression, spatial frequency filtration, motion detector, edge enhancement, and contrast enhancement.

Intended Use:

The Siremobil Compact is a mobile x-ray system intended for use in Operating room, Traumatology, Endoscopy, Intensive Care Station, Pediatrics, Ambulatory patient care and in Veterinary Medicine. The Siremobil Compact can operate in four different modes, Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy and cassette exposures which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of a intra-medullary nail implants in various positions, low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

Technological Characteristics:

The Siremobil Compact is designed for an optimal range of movement. The rotational, orbital, and angulation movement ranges for the C-arm are as follows: ± 12.5 °, 125° (-35 to +90) orbital movement and ± 190° angulation. The horizontal and vertical movement of the C-arm is optimized for use in clinical applications. The horizontal travel is 20 cm (7.9") and the vertical travel is 45 cm (17.7"). The large C-arm depth, 66 cm (29"), provides the user with excellent patient access during examinations.

General Safety and Effectiveness Concerns:

Instructions for use are included within the device labeling and the information provided will enable the trained healthcare professional to operate the device in a safe and efficacious manner. 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.

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Substantial Equivalence:

The Siremobil Compact, Mobile X-ray System, has similar technological characteristics and intended uses as the predicate devices described in the Equivalency Information section of this premarket notification. Also, the Laser Targeting Devices (one unit attached to the image intensifier and one unit to attached to the x-ray tube) configured with the Siremobil Compact are the same as the device currently configured with the commercially available Siremobil 2000.

Siemens Medical Systems, Inc. believes that the Siremobil Compact, the subject of this premarket notification, is substantially equivalent to the following medical devices currently in commercial distribution.

Model	Company	FDA K-Number
Siremobil 2000	Siemens Medical Systems, Inc.	K913525
Stenoscop 6000/9000	General Electric, Inc.	K910902
BV 29	Philips, Inc.	K910115
Series 9600	OEC, Inc.	K926056

Kathleen Rutherford
Manager, Regulatory Submissions

8/7/96
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

NOV 17 2011

Ms. Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.
186 Wood Avenue South
ISELIN NJ 08830

Re: K963093
Trade/Device Name: Siremobil Compact Mobile X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image intensified fluoroscopic x-ray system, mobile
Regulatory Class: II
Product Code: OXO
Dated: August 7, 1996
Received: August 8, 1996

Dear Ms. Rutherford:

This letter corrects our substantially equivalent letter of September 3, 1996.

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 (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 contact 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.

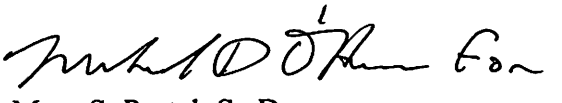
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

CONFIDENTIAL

510(k) Number (if known): K963093
Device Name: Siremobil Compact

Indications For Use:

The Siremobil Compact is a mobile x-ray system intended for use in Operating room, Traumatology, Endoscopy, Intensive Care Station, Pediatrics, Ambulatory patient care and in Veterinary Medicine. The Siremobil Compact can operate in four different modes, Digital Radiography, Fluoroscopy and Pulsed Fluoroscopy and Cassette exposure which are necessary in performing wide variety of clinical procedures, such as intraoperative bile duct display, fluoroscopic display of intra-medullary nail implant in various positions, low dose fluoroscopy in pediatrics, fluoroscopic techniques utilized in pain therapy and positioning of catheters and probes.

Concurrence of the CDRH, Office of Device Evaluation (ODE)

David A. Legorsen
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K963093

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)