SIEMENS

510(k) Summary

NOV 10 1997

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: (732) 321- 4779
  Telefax: (732) 321 - 4841

Date of Summary Preparation:

Device Name:

- Trade Name: Siremobil C02
- 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 C02 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 C02 is designed to meet the space and clinical requirements of the clinical environments identified below.

The Siremobil C02 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 C02 can operate in six modes: Fluoroscopy with Last Image Hold, Pulsed Fluoroscopy with Last Image Hold, Digital Radiography, Cassette Exposures, Digital Subtraction, and Roadmapping. 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 C02 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 C02 can operate in six modes: Fluoroscopy with Last Image Hold, Pulsed Fluoroscopy with Last Image Hold, Digital Radiography, Cassette Exposures, Digital Subtraction, and Roadmapping, 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 C02 is designed for an optimal range of movement. The orbital range for the C-arm is 190° and the angulation movement range is ±190°. The horizontal swivel (rotational) range is ±12.5°. The horizontal and vertical movement of the C-arm is optimized for use in clinical applications. The horizontal travel is 20 cm and the vertical travel is 40 cm. The large C-arm depth or interior width of C-arm, 74 cm, provides the user with excellent patient access during examinations.

- Isocentric C-arm
- Expanded orbital angle of 190°
- Increased distance between X-ray tube and image intensifier (SID)
- Electromagnetic brakes, instead on manual brakes
- Concealed, integrated cable routing
- Interfaces available to allow for the use of the C-arm system with other commercially available medical systems. The premarket approval of these interfaced medical devices will be obtained in a separate filing to FDA prior to commercialization.

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: K973598
Trade/Device Name: Sireobil C02 (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: September 19, 1997
Received: September 22, 1997

Dear Ms. Rutherford:

This letter corrects our substantially equivalent letter of November 10, 1997.

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,

for

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

510(k) Number (if known): _____
Device Name: Siremobil C02

Indications For Use:

The Siremobil C02 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 C02 can operate in six different modes: Digital Radiography, Fluoroscopy, Pulsed Fluoroscopy, Cassette Exposures, Digital Subtraction, and Roadmapping, 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)

Carol C. Benson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973598

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