K040347

MAR - 9 2004

# 510(K) SUMMARY
## FOR THE
## SIREMOBIL ISO-C 3D

Submitted by:

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

February 10, 2004

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. **Contact Person:**
Ms. Nealie Hartman
51 Valley Stream Parkway
Malvern, PA 19355
Phone: (610) 448-1769
Fax: (610) 448-1787

2. **Device Name and Classification:**

| | |
|---|---|
| Trade Name: | Siremobil Iso-C 3D |
| Classification Name: | Mobile X-Ray System |
| Classification Panel: | Radiology |
| CFR Section: | 21 CFR §892.1720 |
| Device Classification: | Class II |
| Product Code: | OXO, JAA |

3. **Substantial Equivalence:**
The Siremobil Iso-C 3D is designed for three-dimensional evaluation of data acquired with an isocentric mobile C-arm device. The package is substantially equivalent to the following devices:

| *Predicate Device Name* | *FDA Clearance Number* | *FDA Clearance Date* |
|---|---|---|
| Siemens Siremobil Iso-C 3D | K032088 | 09/10/03 |

K040347

4. **Device Description:**
The Siremobil Iso-C 3D is an isocentric 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 3D imaging option allows the reconstruction of two-dimensional images acquired with a mobile isocentric C-arm device into a three-dimensional image format.

5. **Intended Use of the Device:**
The Siremobil Iso-C 3D is designed as a 3D imaging device and is intended to be used whenever the physician benefits from intraoperatively generated 3D information of high contrast objects and anatomical structures.

6. **Summary of Technological Characteristics of the Devices Compared to the Predicate:**
The Siemens Siremobil Iso-C 3D with extended Indications for Use and the predicate devices allow reconstruction of a three-dimensional model from a series of two dimensional images acquired with a C-arm imaging device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Nealie Hartman
Technical Specialist, Regulatory Affairs
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway J-15
MALVERN PA 19355

MAY 22 2012

Re: K040347
Trade/Device Name: Siremobil ISO-C 3D
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO and JAA
Dated: February 10, 2004
Received: February 12, 2004

Dear Ms. Hartman:

This letter corrects our substantially equivalent letter of November 14, 2011.

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

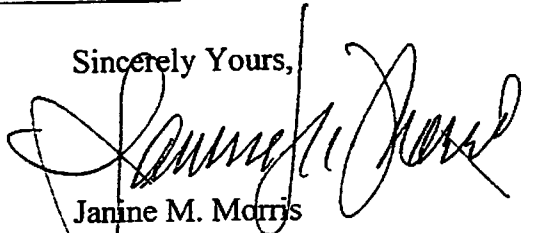
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting 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):** K040347
**Device Name:** Siremobil Iso-C 3D

**Indications For Use:**

The Siremobil Iso-C 3D with extended Indications for Use is based on Siemens isocentric mobile C-arm, marketed as Siremobil Iso-C 3D. The extended Indications for Use include the high contrast objects and anatomical structures of the entire body. The Siremobil Iso-C 3D contains no new hardware or software.

The Siremobil Iso-C 3D is designed as a 3D imaging device and is intended to be used whenever the physician benefits from intraoperatively generated 3D information of high contrast objects and anatomical structures.

(Please do not write below this line - continue on another page if needed)

---

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

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

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040347