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K033238

510(K) SUMMARY
FOR THE
MOBILETT XP AND MOBILETT XPHYBRID

Submitted by:

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

September 26, 2003

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:	Mobilett XP and Mobilett XP_{Hybrid}
Classification Name:	Mobile X-Ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1720
Device Classification:	Class II
Product Code:	IZL

3. Substantial Equivalence:

The Mobilett XP and Mobilett XP_{hybrid} x-ray systems are microprocessor controlled mobile x-ray systems developed for routine bedside radiographic procedures. The systems are substantially equivalent to the following devices:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens Mobilett Plus/Mobilett Plus HP	K932106	09/14/94

4. Device Description:

The Mobilett XP and Mobilett XP_{hybrid} x-ray systems are microprocessor controlled mobile x-ray systems developed for routine bedside radiographic procedures in intensive care, emergency, central X-ray, and pediatric departments, as well as operating rooms.

5. Intended Use of the Device:

The Mobilett XP and Mobilett XP_{hybrid} are radiographic systems designed for use in wards, intensive care and premature-birth wards, pediatric and emergency departments, operating theatres as well as the central X-ray department.

Nealie K. Hartman

Nealie Hartman
Technical Specialist, Regulatory Affairs Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Ms. Nealie Hartman
Technical Specialist Regulatory Affairs
Siemens Medical Systems, Inc.
51 Valley Stream Parkway
MALVERN PA 19355

Re: K033238
Trade/Device Name: Mobilett XP and Mobilett XP Hybrid
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobil x-ray system
Regulatory Class: II
Product Code: 90 IZL
Dated: October 3, 2003
Received: October 17, 2003

Dear Ms. Hartman:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033238
Device Name: **Mobilett XP and Mobilett XP_{hybrid}**

INDICATIONS FOR USE:

The Mobilett XP and Mobilett XP_{hybrid} are radiographic systems designed for use in wards, intensive care and premature-birth wards, pediatric and emergency departments, operating theatres as well as the central X-ray department.

(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 K033238