NOV - 5 1999

ATTACHMENT 11

510(K) SUMMARY K992660

URF Digital - OT

Submitted by:
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

August 6, 1999

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. Malgorzata Stanek
Phone: (732) 321-3950 Fax: (732) 321-4841

2. **Device Name and Classification**

Trade Name:	URF Digital - OT
Classification Name:	Image Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.1650
Device Class:	Class II
Device Code:	90JAA 90WB

3. **Intended Use**

The URF Digital - OT is a device intended to visualize anatomical structures by converting a pattern of X-ray into a visible image through electronic amplification. The system has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract. The units may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA).

4. **Substantial Equivalence**

The URF Digital - OT is substantially equivalent to Siemens Siregraph T.O.P. 33 and 40 that are currently in commercial distribution. The Siregraph T.O.P. 33 and 40 were described in premarket notification K970734, which received FDA clearance on April 21, 1997.

5. **Device Description**

URF Digital - OT is a universal fluoroscopic X-ray diagnostic system intended for use in Digital Fluoro Radiography (DFR) with an undertable image intensifier. The system is operated either via tableside control or via remote control console.

The URF Digital - OT is available in two versions, the URF Digital - OT TOP and the URF Digital - OT Comfort.

6. **Summary of Technological Characteristics of the Principal Device as Compared with the Predicate Device**

The URF Digital - OT has the same technological characteristics as the predicate Siregraph T.O.P 33 and 40. Like the Siregraph T.O.P 33 and 40, the URF Digital - OT consists of the basic system (patient support table) and standard system components (i.e. X-ray generator, X-ray tube, image intensifier, TV system, digital imaging system, monitors, optional Bucky wall stand and optional ceiling-mounted support for a second X-ray tube).

The Siregraph TOP and the URF Digital - OT differ such that, in the URF Digital - OT:

- The basic system and system stand are created from modular components for higher flexibility.
- A new digital imaging system with CCD camera has been added.
- The unit is configured with the latest commercially available system components.

Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Malgorzata Stanek
Senior Technical Specialist
Siemens Medical Systems, Inc.
186 Wood Ave., South
ISELIN NJ 08830

MAY - 7 2012

Re: K992660
Trade/Device Name: URF Digital-OT Image-Intensified Fluoroscopic X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: August 6, 1999
Received: August 9, 1999

Dear Ms. Stanek:

This letter corrects our substantially equivalent letter of November 5, 1999.

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

ATTACHMENT 1

INDICATIONS FOR USE

510(k) Number (if known): K992660

Device Name: URF Digital - OT

Indications for Use:

The Siemens URF Digital - OT is intended to visualize anatomical structures by converting a pattern of X-ray into a visible image through electronic amplification. The system has medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures, as well as examination of the urogenital tract. The URF Digital - OT may also be used in lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA).

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

David A. Legmm

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992660

Prescription Use X OR Over-The-Counter Use _____
(per 21 CFR 801.109)