APR 21 1997

SIEMENS

K970734

Attachment 12

510(k) Summary

Siregraph T.O.P. 33 and Siregraph T.O.P. 40

Submitted by:

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

February 27, 1997

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. Jing Zhang
Phone: (908)321-4927 Fax: (908)321-4841

2. **Device Name and Classification:**

Trade Name:	Siregraph T.O.P. 33 and Siregraph T.O.P. 40 Universal Fluoroscopic X-ray Systems
Classification Name:	Image Intensified Fluoroscopic X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1650
Device Class:	Class II
Device Code:	90JAA 1 OWB

3. **Intended Use:**
The Siregraph T.O.P. 33 and T.O.P. 40 Universal Fluoroscopic X-ray Systems are devices intended to visualize anatomical structures by converting a pattern of X-ray into a visible image through electronic amplification. Both systems have medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract, lymphography, endoscopy, myelography, venography, pediatrics, arthrography, interventional radiology, digital angiography, and digital subtraction angiography (DSA).

4. **Substantial Equivalence:**
The Siregraph T.O.P. 33 and 40 are substantially equivalent to the following devices in commercial distribution:

- Siregraph D3 and D340, K860913
  Siemens Medical Systems, Inc.
- Siregraph CF, K960266
  Siemens Medical Systems, Inc.

5. **Device Description:**
Siregraph T.O.P. is a universal fluoroscopic X-ray diagnostic system with an overtable X-ray tube assembly. Two versions are available: Siregraph T.O.P. 33 for use with an undertable spot film device, and Siregraph T.O.P. 40 for use in Digital Fluoro Radiography(DFR) with an undertable Image Intensifier (I.I.). Both systems are operated either via table side control or the remote control console.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Devices:**
Siregraph T.O.P. has the same technological characteristics as the predicate Siregraph D3/D340. Both systems are remote fluoroscopic X-ray diagnostic systems with an overtable X-ray tube assembly. Like Siregraph D3 and D340, Siregraph T.O.P. consists of the basic system (patient support table), and standard system components: X-ray generator, X-ray tube, Image Intensifier, TV system, digital imaging system, monitors, optional Bucky wall stand and optional ceiling-mounted support for second X-ray tube. The differences between Siregraph D3/D340 and Siregraph T.O.P. are:

- The Siregraph T.O.P. basic system is redesigned for better ergonomics.
- The communication network among system components (e.g., generator, tube, etc.) has been updated. The XCS communication system is employed.
- Siregraph T.O.P. are 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. Kathleen Rutherford
Manager, Regulatory Submissions
Siemens Medical Systems, Inc.
186 Wood Avenue South
ISELIN NJ 08830

FEB 19 2013

Re: K970734
Trade/Device Name: Siregraph T.O.P. 33 and Siregraph T.O.P 40
Universal 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: February 27, 1997
Received: February 28, 1997

Dear Ms. Rutherford:

This letter corrects our substantially equivalent letter of April 21, 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 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): K970734

Device Name: Siregraph T.O.P. 33 and Siregraph T.O.P. 40

Indications for Use:

The Siregraph T.O.P. 33 and Siregraph T.O.P. 40 Universal Fluoroscopic X-ray Systems are devices intended to visualize anatomical structures by converting a pattern of X-ray into a visible image through electronic amplification. Both systems have medical applications ranging from gastrointestinal examinations to cranial, skeletal, thoracic and lung exposures as well as examination of the urogenital tract, 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. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K970734

Prescription Use ✓ OR Over-The-Counter Use ______
(per 21 CFR 801.109)

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