K993947

DEC 21 1999

Attachment 11

510 (k) Summary

Koordinat Angiographic and Operating Room Model X-Ray Table Family

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

November 22, 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 Alicia Juergensen
Phone: (908) 321-3243 Fax: (908)321-4841

2. **Device Name and Classification:**

Trade Name:	Koordinat Angiographic and Operating Room Model X-Ray Table Family
Classification Name:	Angio X-Ray System Accessory
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1600
Device Class:	Class II

3. **Intended Use:**

The Siemens Koordinat Angiographic X-ray Table family is intended to support and position patients for Angiographic examinations, Angiographic interventional techniques where an X-ray translucent tabletop is required, and for use during surgery where an X-ray translucent tabletop is required.

4. **Substantial Equivalence:**

The new Koordinat OR models are substantially equivalent to the following device in commercial distribution:

- Koordinat M Table, K951176 cleared on 4/30/95
  Siemens Medical Systems, Inc.
- OP/PTCA-System 1520, K883613 cleared on 9/15/88
  Maquet
- Synchra Tilt, K940696 cleared on
  Philips
- 90/50 Mobile Imaging Table, K884531 cleared on1/11/89
  Beta Medical System

5. **Device Description**

The Koordinat Table family is a modification to an existing floor mounted X-ray table for angiographic examinations and interventions, and surgery. The modified Koordinat table is based on knowledge and experience gained with the predecessor model, the Koordinat M Table. The Koordinat M was described in the 510(k) Submitted on 4/30/95 with the number K951176.

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

The Kordinat Table has the same technological characteristics as the predicate Koordinat M table. Like the Koordinat M the Koordinat OR family can be connected to several existing angiographic x-ray systems (i.e. Angiostar Plus and Multistar Plus).

The difference is demonstrated in the higher two models which will no longer utilize analog interface but will provide a CAN bus interface to report table position to the angiographic x-ray system. Table movements will also be controlled via the CAN bus interface.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 1999

Alicia Juergensen
Technical Specialist
Regulatory Affairs
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, NJ 08830

Re: K993947
Kooridinat OR, AXIUM, AXIOM OR Angiographic and Operating Room Model X-Ray Table Family
Dated: November 19, 1999
Received: November 22, 1999
Regulatory class: II
21 CFR 892.1600/Procode: 90 IZI

Dear Ms. Juergensen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

Indications for Use

510(k) Number (if known): K993947

Device Name: Koordinat Angiographic X-Ray Table

Indications for Use:

The Siemens Koordinat Angiographic X-ray Table family is intended to support and position patients for Angiographic examinations, Angiographic interventional techniques where an X-ray translucent tabletop is required, and for use during surgery where an X-ray translucent tabletop is required.

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

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

David G. Segan
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993947