4/21/99

ATTACHMENT 12

K983732

510(K) SUMMARY

Flat Panel Detector
Submitted by:

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

October 21, 1998

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:	THORAX FD
Classification Name:	Solid State X-ray Imager (SSXI)
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1680 Stationary X-ray System
Device Class:	Class II
Product Code:	90MQB

Trade Name:	MULTIX FD
Classification Name:	Solid State X-ray Imager (SSXI)
Classification Panel:	Radiology
CFR Section:	21 CFR §892.1680 Stationary X-ray System
Device Class:	Class II
Product Code:	90MQB

3. **Substantial Equivalence:**

The Flat Panel Detector is designed for use in the MULTIX FD and the THORAX FD stationary x-ray systems. These configurations allow acquisition of radiographic exposures of various anatomical regions of the body. They are substantially equivalent to the following SIEMENS Medical Systems devices:

SIEMENS Device Name	System Type	FDA Clearance Number	FDA Clearance Date
DIGISCAN 2	Phosphor Plate System	K924459	12/17/92
THORAMAT	Vertical Chest X-ray System	Pre-Ammendment	Pre-Ammendment
Multix TOP/PRO	Stationary X-ray System	K971452	5/14/97

4. **Device Description:**

The SIEMENS Flat Panel Detector is a scintillator-photodetector device. The Flat Panel Detector is used in two different configurations which allow acquisition of radiographic exposures. The two configurations in which the detector is used are the vertical position, marketed as the THORAX FD, and the horizontal position, marketed as the MULTIX FD. Both x-ray system configurations utilize the digital capabilities of the detector, in conjunction with other system components, to produce radiographic images of various anatomical regions of the body.

The SIEMENS Flat Panel Detector, in the THORAX FD and the MULTIX FD configurations, allows acquisition of exposures without the use of conventional film/screen systems. This process is done via semiconductor sensors which facilitate direct conversion of x-ray quanta into digital image data.

5. **Intended Use of the Device:**

The SIEMENS Flat Panel Detector, in both the THORAX FD and the MULTIX FD systems, allows acquisition of exposures without the use of conventional film/screen systems. The THORAX FD system is a stand alone automated chest unit, while the MULTIX FD is a universal radiographic x-ray system. The MULTIX FD and the THORAX FD both allow radiographic exposures of the whole body including skull, spinal column, chest, abdomen, extremities, and excluding mammography. Radiographic exposures may be taken with the patient in the sitting, standing, or prone positions.

6. **Summary of Technological Characteristics of the Devices Compared to the Predicate:**

Both configurations, THORAX FD and MULTIX FD, are capable of acquiring radiographic images in a manner similar to that of the in the DIGISCAN 2, the THOROMAT, and the Multix TOP/PRO. The difference is that the THORAX FD and the MULTIX FD systems use SSXI digital technology, as opposed to the predicates which use standard film or phosphor plate technology.

7. **Clinical Study and Conclusion:**

A clinical study were carried out in Regensburg, Germany to determine whether radiographic images taken using the digital technology of the THORAX FD and the MULTIX FD systems were substantially equivalent to standard film images. The results from the studies showed that the digital images were comparable to film. Laboratory test results also support the equivalence to standard film images shown in the clinical studies. This clinical outcome supported the diagnostic imaging quality of the digital system as being equal to or better than film/screen.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 1999

Malgorzata Stanek
Technical Specialist, RAC
Siemens Medical Systems, Inc.
186 Wood Avenue South
Iselin, New Jersey 08830

RE: K983732
Thorax FD & Multix FD Solid State
X-Ray Imaging Systems
Dated: January 27, 1999
Received: January 28, 1999
Regulatory Class: II
21 CFR 892.1630/Procode: 90 MQB

Dear Ms. Stanek:

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 13

INDICATIONS FOR USE

510(k) Number (if known): K983732
Device Name: **Flat Panel Detector in the THORAX FD and MULTIX FD**

Indications For Use:

The SIEMENS Flat Panel Detector, in both the THORAX FD and the MULTIX FD systems, allows acquisition of x-ray exposures without the use of conventional film/screen systems. The THORAX FD system is a stand alone automated chest unit, while the MULTIX FD is a universal radiographic x-ray system. The MULTIX FD and THORAX FD both allow radiographic exposures of the whole body including skull, spinal column, chest, abdomen, extremities, and excluding mammography. Radiographic exposures may be taken with the patient in the sitting, standing, or supine positions.

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

David G. Segerson

Sign-Off)
of Reproductive, Abdominal, ENT,
Radiological Devices
(k) Number K983732

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)