K982028

SIEMENS

JUL 14 1998

APPENDIX 1

510(k) Summary
Fluorospot Compact

Submitted by:

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

June 8, 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:	Fluorospot Compact
Classification Name:	Image Intensified Fluoroscopic X-ray System
CFR Section:	21 CFR §892.1650, Class II
Device Code:	90JAA

3. Substantial Equivalence:

The Fluorospot Compact is substantially equivalent to the following Siemens Medical Systems' devices:

1) Fluorospot T.O.P
K961871, cleared by FDA on July 31, 1996

2) Fluorospot H (Version 2)
K914525, cleared by FDA on November 19, 1991

Fluorospot H (Version 1)
K911082, cleared by FDA on May 1, 1991

4. Device Description:

The Fluorospot Compact is a PC-based, 10 bit acquisition digital imaging system where images are acquired in 1024^2 format. It can be configured with conventional over-table/under-table x-ray systems (e.g. commercially available Sireskop SX and Siregraph CX). Configuring the conventional systems with Fluorospot Compact provides the

systems with multi-functional use capability, thus allowing trained healthcare professionals to perform x-ray imaging using conventional film or digital imaging. Upon acquiring digital images, the user can display them on the live monitor in the exam room, as well as the control room for review. Multiple digital image acquisition and storage is possible without interrupting the procedure to change film.

5. **Intended Use of the Device:**
The Fluorospot Compact digital imaging system, is an optional integral component of a radiographic/fluoroscopic x-ray system, and as such it is not considered a stand alone device. The Fluorospot Compact is intended for use with x-ray systems to digitally acquire, record and display radiographic images. The Fluorospot Compact enables the trained healthcare professional to consistently acquire high quality images for fluoroscopic examinations with contrast medium, urological examinations as well as vascular and non-vascular procedures.

6. **Summary of Technological Characteristics of the Device Compared to the Predicate Device:**
The Fluorospot Compact has the same technological characteristics as the predicates Fluorospot T.O.P. and Fluorospot H. They utilize PC based technology to acquire, store and post process images from the image intensifier/TV chain output of an image intensified fluoroscopic system.

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

JUL 14 1998

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

Re: K982028
Fluorospot Compact
Dated: June 8, 1998
Received: June 9, 1998
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA

Dear Mr. 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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX 2

INDICATIONS FOR USE

510(k) Number (if known): _____
Device Name: **Fluorospot Compact**

Indications For Use:

The Fluorospot Compact digital imaging system, is an optional integral component of a radiographic/fluoroscopic x-ray system, as such it is not considered a stand-alone device. The Fluorospot Compact is intended for use with x-ray systems to digitally acquire, record and display radiographic images. The Fluorospot Compact enables the trained healthcare professional to consistently acquire high quality images for fluoroscopic examinations with contrast medium, urological examinations as well as vascular and non-vascular procedures.

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

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982028

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