SEP 9 1999

RAYPAX

510(k) Summary of Safety and Effectiveness

K992112

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
June 15, 1999

Submitter's Information: 21 CFR 807.92(a)(1)
SAMSUNG SDS CO., LTD
707-19, Yoksam-Dong, Kangnam-Gu,
Seoul, Korea, 135-080

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)
Trade Name: Samsung RAYPAX™ Film Digitizer System
Common Name: Laser Film Digitizer
Device Classification: 21 CFR 892.2040

Predicate Device: 21 CFR 807. 92(a)(3)
Manufacturer: VIDAR SYSTEMS CORPORATION
Device: VXR-LS Laser Film Digitizer
510(k) Number: K974315
Date Received: 11/17/97
Decision Date: 04/17/98
Decision: Substantially Equivalent
Panel Code device reviewed by: Radiology
Panel Code device classified by: Radiology
Product Code: 90 LMA
Classification: Class II

Device Description: 21 CFR 807 92(a)(4)
The Samsung Film Digitizer (FD) can be part of the RAYPAX PACS (Picture Archiving and Communication System), or can be a separate device for other manufacturer's PACS. It converts analog films to digitized images in the DICOM (Digital Imaging and Communications in Medicine) Standard 3 compatible files. In addition, FD supports a patient information search, an image information management, digitization, a DICOM file generation, a simple image processing, and DICOM file transferring to other components of the PACS.

Indications for Use: 21 CFR 807 92(a)(5)
The Samsung RAYPAX™ Film Digitizer is a digitizer intended to convert medical images and data into digital signals. The digital data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the above referenced device contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

1. RAYPAX™ system has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

3. The submission contains the results of a hazard analysis. All potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 1999

Samsung SDS Co., Ltd.
C/o Carl Alletto.
Otech, Inc.
2001 East Oakshores Drive
Crossroads, Texas 76227

Re: K992112
Samsung RAYPAX™ Film Digitizer
Dated: June 7, 1999
Received: June 22, 1999
Regulatory Class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Alletto:

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

(Indications for Use Form)

510(k) Number: K992112

Device Name:

Samsung SDS Co. Ltd. RAYPAX™ Film Digitizer System

Indications for Use:

The Samsung RAYPAX™ Film Digitizer is a digitizer intended to convert medical images and data into digital signals. The digital data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations.

Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992112