



OCT 13 1999 **510(k) Summary of Safety and Effectiveness**

K992426

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

**Date Prepared:**

July 16, 1999

**Submitter's Information:** 21 CFR 807.92(a)(1)

SAMSUNG SDS CO., LTD  
707-19, Yoksam-Dong, Kangnam-Gu,  
Seoul, South Korea, 135-080

**Trade Name, Common Name and Classification:** 21 CFR 807.92(a)(2)

Trade Name: Samsung RAYPAX™ Web Clinical System  
Common Name: Digital Imaging Workstation  
Classification Name: System, Digital Image Communication Accessory  
Device Classification: 21 CFR 892.2010

**Predicate Device:** 21 CFR 807.92(a)(3)

The Samsung SDS Co. Ltd. RAYPAX™ WCS is substantially equivalent to the:

Manufacturer: SECTRA IMTEC AB  
Device Name: Wise II Image Management System  
510(k) Number: K983447  
Date Received: 9/30/98  
Decision Date: 10/29/98  
Decision: Substantially Equivalent  
Panel Code device reviewed by: Radiology  
Panel Code device classified by: Radiology  
Product Code: 90 LMB  
Classification: Class I

**Device Description:** 21 CFR 807.92(a)(4)

The Web-Clinical System (WCS) is a component of the RAYPAX System, a PACS solution by Samsung or can be a separate device for other manufacturer's PACS. The WCS is a system for managing radiological images and data by retrieving and browsing medical images through the World Wide Web, (Internet), a clients Intranet or over computer networks.

**Indications for Use:** 21 CFR 807.92(a)(5)

The Web Clinical System is intended for the management and displaying of x-ray images, other radiological objects, and information. It can manage images from different modalities, single and multiple file servers, and interfaces to various Radiological Information Systems (RIS), image storage and printing devices using DICOM or similar interface standards within the system or across computer networks at distributed locations.



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

**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 WCS contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

1. The RAYPAX™ WCS system has been designed and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.
2. The submission contains the results of a hazard analysis and all potential hazards have been classified as Minor.



OCT 13 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Carl Alletto  
Samsung SDS Co. Ltd.  
C/O Otech, Inc.  
2001 East Oakshores Drive  
Aubrey, Texas 76227Re: K992426  
RAYPAX™ Web Clinical System (WCS)  
Dated: July 16, 1999  
Received: July 21, 1999  
Regulatory class: I  
21 CFR 892.2020/Procode: 90 LMD

Dear Mr. Alletto:

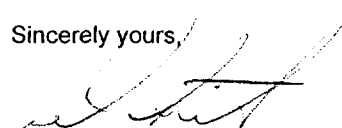
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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: K992426

**Device Name:**

Samsung SDS Co. Ltd. RAYPAX™ Web Clinical System

**Indications for Use:**

The Web Clinical System is intended for the management and displaying of x-ray images, other radiological objects, and information. It can manage images from different modalities, single and multiple file servers, and interfaces to various Radiological Information Systems (RIS), image storage and printing devices using DICOM or similar interface standards within the system or across computer networks at distributed locations.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*David R. Ferguson*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K992426

Prescription Use              
(Per 21 CFR 801.109)

OR

Over-The-Counter Use           

(Optional Format 1-2-96)