

FEB 13 1998

Summary of Safety and Effectiveness

**CLASSIFICATION NAME:** The proposed classification is 21CFR892.2050 (FR 63774, Dec 2, 1997) This device is regulated as Class II Tier I.

**COMMON/USUAL NAME:** PACS System

**TRADE/PROPRIETARY NAME:** iiSYS PACS System

**ESTABLISHMENT No.** 1043882

**PREDICATE DEVICE**

There are no significant differences between the System and its assembled component devices other than the guaranteed connectivity provided by the integration testing. The integration of the devices into the Sterling Diagnostic Imaging iiSYS PACS System is accomplished via comprehensive testing protocol.

There is no change in intended use from the component devices. There is no change in indications for use of the component devices. The intended use and indications for use of the system is the compiled uses of the integrated components.

**REASON FOR 510(k):**

The submission is being made to identify Sterling Diagnostic Imaging, Inc. as offering a complete PACS System which may become a separate device category under proposed regulations. All integral parts of the system have been previously reviewed and cleared by the Agency.

**SYSTEM DESCRIPTION:**

The iiSYS PACS System is a full featured PACS System capable of transmission, archive, display, and print of patient image and demographic information. Its purpose is to facilitate these operations utilizing shared data to promote the availability of information at remote facilities and at locations other than that at which it was acquired. Data may be received as digital information, video signals, or hard copy prints and may be reviewed via monitor or printed hardcopy. The iiSYS PACS system consists of the following major components:

- Series of Viewing and Reading Workstations
- Teleradiology devices for digitizing and transmission of images over wide area or local area networks for remote or at home review
- Archive for short or long term storage
- LINX Network system for secondary capture and transmission of images to other devices (workstation, telerad, printers, etc.)
- Printers

The major elements of the System are previously cleared devices as identified in the following submission. Sterling is not altering the specifications, claims, indications, or intended use of any component. The Sterling iiSYS PACS System is a compilation of components that has been professionally tested to insure their connectivity and efficiency when utilized together. This testing is optimized to give the user assurance that the devices will provide a maximum value-added to the clinical environment without impacting safety or efficacy of the individual components. Connectivity and compatibility are evaluated and ensured via the Integration Test Protocol.

**INTENDED USE**

The iiSYS PACS System is a complete PACS System for the Transmission, Display, Archive, and printing of patient images and demographic information. The system is indicated for the assembly, organization, sharing, and display of patient images and demographic information for diagnostic and referral purposes.

Application areas include radiologist central reading rooms or any location where a medical professional would require or desire access to patient image and demographic information.

**SAFETY INFORMATION:**

The System has no patient contacting materials and is utilized only by trained professionals. The output of the device is evaluated by additional trained professionals allowing sufficient review to afford identification and intervention in the event of a malfunction. The device does not impact the quality or status of the original acquired image data.

Selection of the specific components of the system has been made to allow the system to remain cost effective and consistent with current technology through the substitution of components as technology develops. By retaining criteria for the substitution of components, any concerns about safety or efficacy and substantial equivalence can be satisfactorily met by a determination that the component substitution is not a significant change in the system. This is consistent with existing Agency guidance.

**CONCLUSION [21 CFR: 807.92(b)(3)]**

The subject device has no patient contact, nor does it control, monitor, or effect any devices directly connected to or effecting such a patient contacting device. The images generated by the subject device is observed by medical personnel, offering ample opportunity for competent human intervention in the event of a failure.

Sterling believes sufficient information is included to reach a determination of substantial equivalence. We conclude that the subject device is as safe and effective as the component devices.



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Food and Drug Administration  
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Rockville MD 20850

Timothy W. Capehart  
Manager of Regulatory Affairs and Compliance  
Sterling Diagnostic Imaging, Inc.  
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Mailstop 102  
P.O. Box 19048  
Greenville, SC 29602-9048

Re: K980220  
iiSYS PACS System  
Dated: January 22, 1998  
Received: January 22, 1998  
Regulatory class: Unclassified  
Procode: 90 LMD

Dear Mr. Capehart:

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 requirement, 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/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

510(k) Number (if known) : K980220

Device Name : iiSYS PACS System

Indications for Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerson

(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K980220

Prescription Use   
(Per 21 CFR 801.109)

Over the Counter Use