K986970

JUN - 8 1998

STERLING®
Diagnostic Imaging

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

SUBMITTED BY: Jean E. Bartlett
Regulatory Affairs
STERLING DIAGNOSTIC IMAGING, INC.
PO Box 19048, Mail Drop 102
Greenville, SC 29602-9048

PREPARATION DATE: March 13, 1998

DEVICE NAME: DirectRay™ Operator Console
Two versions: (a) Parallel
(b) Integrated

There are two versions of the device covered by this premarket notification, the **Parallel** version and the **Integrated** version, and the classification information is slightly different for the two versions:

CLASSIFICATION and PROCODE:

Parallel: 21CFR 892.2050 (Proposed)- PACS Device (90 LMD)
and accessory to:
Unclassified - Solid-State Digital X-Ray Device(90MQB)

Integrated: 21CFR 892.2050 (Proposed) - PACS Device (90 LMD)
21CFR 892.1680 -Stationary X-Ray System (90KPR)
and accessory to:
Unclassified - Solid-State Digital X-Ray Device(90MQB)

PREDICATE DEVICES: In both versions, the DROC is an accessory to the DirectRay™ digital image capture device (K#973206).

Parallel: LINX™ Networking System - K964250

Integrated: MicroX-80 HF - K944149
(X-ray console functions only)

Sterling Diagnostic Imaging, Inc.
10 South Academy Street
P.O. Box 19048
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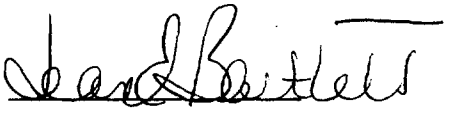
DEVICE DESCRIPTION: The DirectRay™ Operator Console is that device, which when used with any X-ray generating equipment and the DirectRay™ device (Sterling Diagnostic Imaging Direct Radiography™ [1] K#973206) allows the synchronization of the ready states of the DirectRay™ device and the X-ray generator, and allows the operator to acquire, preview and transmit image and associated text data along with exam administration report capabilities. In one version, this device will also integrate these functions with the typical functions of an X-ray console eliminating the need for a separate X-ray console. This device is located in the control booth and will usually be housed in a specially designed cabinet. An optional feature of the DROC is the ability to link the digital image with the hospital information/radiology information systems (HIS/RIS).

INTENDED USE: To provide a network connection to various output (e.g. hardcopy, softcopy and archive) devices from any radiographic device which uses the DirectRay™ Image capture system.

To synchronize the ready states of the DirectRay™ device and the radiographic equipment. When a single X-ray console is desired, to provide the X-ray console features (e.g. technique selection) of the radiographic equipment.

COMPARISON TO PREDICATE DEVICE(s): The DROC brings together the features of the LINX™ Networking System and the X-ray console functions of the Micro X-80 into a single device. With respect to the synchronization of the ready states of the DirectRay™ device and the radiographic equipment, the DROC is considered an accessory to the DirectRay™.

Signature 

Date March 13, 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 1998

Jean E. Bartlett
Regulatory Affairs Manager
Sterling Diagnostic Imaging
10 South Academy Street
Mailbox 120
P.O. Box 19048
Greenville, SC 29602-9048

Re: K980970
iiRAD™ Operator Console
Dated: March 13, 1998
Received: March 16, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Ms. Bartlett:

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

INDICATIONS STATEMENT

510(k) Number (if known): K980970

Device Name: DirectRay™ Operator Console

Indications for Use:

The DirectRay™ Operator Console has application whenever the transmission of radiographic images and associated patient text data is desired to take place from an input device, such as any radiographic equipment which uses the DirectRay™ device, to any output device, such as hardcopy, softcopy, or archive devices.

(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 _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Seyson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980970