STERLING®
Diagnostic Imaging

K973206

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 21CFR 807.92.

DEC - 4 1997

Submitter's Name:

Elaine H. Kindell
(302) 631-3423
Sterling Diagnostic Imaging, Inc.
P. O. Box 6020
Route 896, Building 600
Glasgow Business Community
Newark, DE 19714-6020
Fax# (302) 631-3483

Date of Preparation: August 22, 1997

Name of Product: Sterling Diagnostic Imaging Direct Radiography™

FDA Classification Name: Solid State X-ray Imaging Device - 90 MBQ

Predicate Device: Radiographic Film (892.1840)
Radiographic Intensifying Screen (892.1960)

Device Description: The Sterling Diagnostic Imaging Direct Radiography™ device is used to directly capture and convert conventional projection X-ray images to digital images. A sub-sampled image can be displayed on a preview monitor for viewing. The diagnostic image can be transmitted through a digital network for diagnostic viewing and printing. The device provides digital image capture for conventional radiographic examinations (excluding fluoroscopic, angiographic, and mammographic applications). The Direct Radiography™ device differs from traditional X-ray systems in that instead of exposing a film for subsequent wet chemical processing to create a hardcopy image, a device called a digital array is used to capture the image in electronic form. The digital data are then used to produce hardcopy and softcopy images.

Intended Use:	The Direct Radiography™ device provides a digital image capture capability for conventional radiographic examinations (excluding fluoroscopic, angiographic, and mammographic applications). The device has application wherever conventional screen-film systems are currently used.
Comparison to Predicate Device:	The Sterling Direct Radiography™ device uses an electronic readout of an image while conventional screen-film systems require chemical processing to produce an image. The Sterling Direct Radiography™ device produces a digital image while conventional screen-film systems produce an analog image.
Comments on Substantial Equivalence:	Both systems are used for conventional radiographic examinations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Elaine H. Kindell
Regulatory Affairs Manager
STERLING™ Diagnostic Imaging, Inc.
Glasgow Business Community
P.O. Box 6020
Newark, DE 19714-6020

Re: K973206
Sterling Diagnostic Imaging
Direct Radiography™
Dated: November 24, 1997
Received: November 25, 1997
Unclassified/Procode: 90 MQB

DEC - 4 1997

Dear Ms. Kindell:

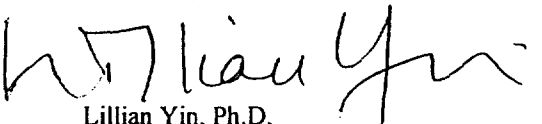
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

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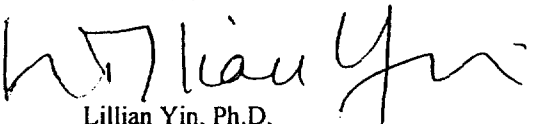

Lillian Yin, Ph.D.
Director, Division of Reproductive,
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and Radiological Devices
Office of Device Evaluation
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Enclosure

Indications Statement

510(k) Number (if known): K973206

Device Name: Sterling Diagnostic Imaging Direct Radiography™

Indications for Use:

The Direct Radiography™ device provides a digital image capture capability for conventional radiographic examinations (excluding fluoroscopic, angiographic, and mammographic applications). The device has application wherever conventional screen-film systems are currently used.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X 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 K973206