

## Summary of Safety and Effectiveness

NOV 10 1997

K972660

### Trade Name, Common Name, Classification

The device trade name is Sterling Raven Dry Imager. The device common names is medical image printer. While officially unclassified, the predicates are assigned to regulatory classification II and are categorized as Multi-Format Cameras, 90LMC.

### Predicate Device

Sterling identifies the predicate devices as the Sterling Lynx LP400 Laser Imager (K912073 August 28, 1991) and the 3M Dry View 8700 Laser Imager. FDA's accession number for the Premarket notification for the predicate devices are K912073 and K945475 respectively. FDA cleared the marketing of the predicate devices in letters dated August 28, 1991 and March 9, 1995.

The primary differences between the devices is that the Raven will deposit ink onto the printing surface while the predicate utilizes a laser print head to affect a film coating or a laser to expose silver halide film.

The software component of the Raven is used for interfacing to the source of the image data as well as controlling hardware components during the actual printing process. Software utilized within the Raven is equivalent to the software used in the predicate devices.

### Description of the Device

The device accepts electrical image signals and produces hard copy images. The image signal source may be analog or digital formatted image data from image readers or unformatted image data from other imaging modalities (e.g. CT, MRI). The Sterling Raven Dry Imager uses the information in the image signals to control discrete elements in a print head which writes on the translating paper or Medical Imaging Film, a thermal recording media. The Raven has no laser, cathode ray tube, or optics. Like the predicate devices, the Raven does not use conventional light-sensitive silver halide photographic media, and thus requires no dark room, film processor, processing chemicals, water, drainage, or dryer ventilation. It produces no chemical waste, and requires no space for chemical storage.

The major elements are the film magazine, transport mechanics, imaging electronics, and head.

### Intended Use

The intended use of the Imager is the production of hard copy images from medical image data

### Technological Characteristics

The subject device, as the predicate, produces monochrome (black-and-white) gray-scale images from medical image data. The media and the technological characteristics are different from routine laser printers. The Raven device uses coated 7mil sheet film and/or paper for recording the image.

The predicate devices expose the film by translating it past a directly modulated scanning laser diode source. The action of the laser causes the image to be recorded in the media. The Raven print head differs from the predicates' in that it physically places the black dye onto the medium rather than attempting to modulate an intermediate medium.

The device accepts electrical image signals and produces hard copy images. The image signal source may be digital formatted image data from image readers or unformatted image data from other imaging modalities (e.g. CT, MRI). The image signal source may be analog or digital. The Sterling Raven Dry Printer uses the information in the image signals to control discrete elements in a print head which writes on translating paper or Medical Imaging Media (polyester). The Raven has no laser, cathode ray tube, or optics. The Raven does not use conventional light-sensitive silver halide photographic media, requires no dark room, film processor, processing chemicals, water, drainage, or dryer ventilation. It produces no chemical waste, and requires no space for chemical storage.

The major elements of the Printer are the film magazine, transport mechanics, imaging electronics, and print head.

#### Conclusion [21 CFR: 807.92(b)(3)]

As the predicates, 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.

While technologically different, the performance of the subject device is similar to that of the predicate, we conclude that the subject devices are as safe and effective as the predicate device.



Food and Drug Administration  
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NOV 10 1997

Timothy W. Capehart  
Manager of Regulatory Affairs  
and Compliance  
Sterling Diagnostic Imaging Inc.  
P.O. Box 6101  
Building 600/Mailbox 630  
Newark, DE 197146101

Re: K972660  
Raven Dry Printer  
Dated: October 21, 1997  
Received: October 23, 1997  
Regulatory class: Unclassified  
21 CFR 892.1670/Procode: 90 LMC

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) : \_\_\_\_\_

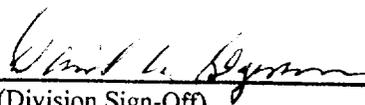
Device Name : Raven Dry Imager

Indications for Use:

The Raven is a free standing device used to print diagnostic images on a polyester base for viewing on a standard view box and/or print reports and referral quality images on paper. It may be used in any situation in which a hard copy of an image generated by a medical imaging device is required or desirable.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K972660

Prescription Use   
(Per 21 CFR 801.109)

Over the Counter Use \_\_\_\_\_