

K973028

STERLING®

Diagnostic Imaging



OCT 28 1997

Summary of Safety and Effectiveness

Helios Laser Imager

CLASSIFICATION NAME: Although this device has not been formally classified by FDA, it has been categorized as 90LMC and is regulated as Class II Tier I

COMMON/USUAL NAME: Multi-Format Imager

TRADE/PROPRIETARY NAME: Helios Laser Imager 1417

ESTABLISHMENT No. 1043882

PERFORMANCE STANDARDS: The device complies with the relevant international and national Safety Standards. It has been manufactured in compliance with ISO9000 and the Quality System Regulation [21 CFR 820].

SYSTEM DESCRIPTION:

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 Helios Laser Imager uses the information in the image signals digitally record diagnostic images and patient data on a proprietary product specific medical imaging media. The Helios 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.

More detailed information regarding the Helios can be found in the preliminary System Specification included in Section 2 as well as Section 4.

EQUIVALENCE INFORMATION:

This submission is for a modification of the previously cleared Helios Laser printer (K912073).

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Mailbox 120
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Greenville, SC 29602-9048

There are two primary differences between the new version of the Helios, referred to as "C" during development, and its predecessor. First is the increased number of lasers to allow the simultaneous printing of 2 lines of image data; thus increasing the throughput. Secondly, the DICOM print server previously located external to the device has now been incorporated into the system.

In addition to the aforementioned modifications, two non-significant modifications are being incorporated into the "C" design. The mechanical sheet feeder has been improved for increased cost efficiency and reliability. The electronics modules have also been consolidated.

These modifications do not change the technology or safety of the Helios printer. The intended use and indications also remain unchanged. The Helios "C" is without question substantially equivalent to its predecessor and is safe and effective for its intended use.

SAFETY INFORMATION:

The results of the hazard analysis, combined with the appropriate preventive measures taken indicate the device is of minor level of concern, as per the August 29, 1991 issue of the *"Reviewers Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review"*.

The device 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.

Sterling Diagnostic Imaging feels that sufficient information and data are contained in this submission to enable CDRH to reach a determination of substantial equivalence within a reasonable time period. In the event that additional information is required, please contact the undersigned or Ms. Debra Hutson.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Timothy W. Capehart
Manager of Regulatory Affairs and Compliance
Sterling Diagnostic Imaging, Inc.
10 South Academy Street
Mailbox 120
P.O. Box 19048
Greenville, SC 29602-9048

Re: K973028
Helios Laser Imager 1417
Dated: August 11, 1997
Received: August 14, 1997
Unclassified
Procode: 90 LMC

OCT 28 1997

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) : K973028

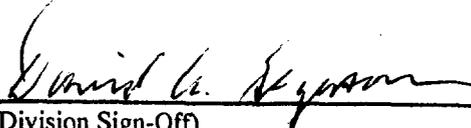
Device Name : Helios Laser Imager

Indications for Use:

The Raven is a free standing device used to print diagnostic images for viewing on a standard view box. 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 K973028

Prescription Use X
(Per 21 CFR 801.109)

Over the Counter Use _____