K973411

2. 510(k) SUMMARY

2.1 Company Name

General Scanning Inc. (GSI)
500 Arsenal Street
Watertown, MA 02172 USA

2.2 Contact Person

Walter J. Leslie
Phone # (617) 924-1010 x197
Fax # (617) 926-0708

DEC - 4 1997

2.3 Date

September 8, 1997

2.4 Device Name

Classification Name	Image Digitizer
Classification Number	90LMA - Radiology Device
Common Name	Film Digitizer
Trade/Proprietary Name	DigMi-2000 (Internal to GSI) LD2800 (Marketing Name)

2.5 Substantial Equivalence - Predicate Devices

Lumiscan 85LF	
Lumiscan 100	K901423
Konica	K933830
Nishimoto Sangyo ED-2000	
Nishimoto Sangyo ED-3500	

2.6 Device Description and "Statement of Indications For Use"

The General Scanning model LD2800 laser film digitizer is intended to create copies of medical images stored on film when connected to a laser imager. It is intended for use in making copies of conventional x-ray films as well as films produced by imagers that fall in the ranges specified for size and optical density range detailed in the specifications.

The digitizer utilizes laser light to scan the film, extracts the image data by measuring the transmitted light, converts it into digital form, and transmits the data over a digital link. A laser imager may then be used to print a copy of the original image.

The LD2800 contains the scanning laser and detection module, a film transport, and electronics to convert and transmit the image data and provide control and calibration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 1997

Walter M. Leslie
Engineering Manager
Optical Scanning Products Division
General Scanning, Inc.
500 Arsenal Street
Watertown, MA 02172

Re: K973411
LD 2800 Film Digitizer
Dated: September 8, 1997
Received: September 9, 1997
Unclassified/Procode: 90 LMA

Dear Mr. Leslie:

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,

William Yin

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): K973411

Device Name: LD2800 (MARKET NAME) DIGMI 2000 (GSI INTERNAL Reference)

Indications For Use:

The General Scanning model LD2800 laser film digitizer is intended to create copies of medical images stored on film when connected to a laser imager. It is intended for use in making copies of conventional x-ray films as well as films produced by imagers that fall in the ranges specified for size and optical density range detailed in the specifications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segmon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973411

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)