

K980565

MAR 19 1998

**2. 510(k) SUMMARY**

**2.1 Company Name** General Scanning Inc. (GSI)  
500 Arsenal Street  
Watertown, MA 02172 USA

**2.2 Contact Person** Steven P. Zis  
Phone # (617) 924-1010 x181  
Fax # (617) 923-1877

**2.3 Date** February 12, 1998

**2.4 Device Name**  
Classification Name Medical Image Digitizer  
Classification Number 90LMA - Radiology Device  
Common Name Laser Film Digitizer  
Trade/Proprietary Name LD2000 SERIES (Marketing Name)

**2.5 Substantial Equivalence - Predicate Devices**

General Scanning LD2800 K973411  
Lumiscan 85LF  
Lumiscan 100 K901423  
Konica K9333830  
Nishimoto Sangyo ED-2000  
Nishimoto Sangyo ED-3500

**2.6 Device Description and "Statement of Indications For Use"**

The General Scanning model LD2000 SERIES laser film digitizer is intended to convert medical images stored on film to digital data for copying, storage, and transmission. It is intended for use to digitize copies of conventional x-rays and films produced by imagers that fall in the ranges 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. The digitized information may then be transmitted to a Laser Imager for printed hardcopy or to a Work Station for use in Teleradiology (transmission of images) or PACS (Picture Archiving Communication Systems).

The LD2000 SERIES contains the scanning laser and detection module, a film transport, and electronics to convert and transmit the image data and provide control and calibration.

### 2.6.1 Principle of Operation - Overview

The digitizer is a system for converting images on x-ray and films into digital data. It accomplishes this by scanning a focused laser beam across the film as the film itself is moved by means of motor-operated rollers. Solid state photo diodes are used to detect the amount of laser light which passes through the film at each pixel. This provides a measure of optical density at each pixel, and this measurement becomes the digital value for that pixel. The aggregate of the digital values for all the pixels on the film being digitized is thus a digital representation of the film's image. The digitizer sends this digital version of the image via an electronic interface.

The table below describes and identifies the main components of the modules that make up the LD2000 SERIES digitizer.

MODULE	DESCRIPTION	MAIN COMPONENTS
Laser	Supplies light beam of appropriate size, wavelength, and power to the Scan.	Laser diode Diode modulator board
Scan	Takes light beam from Laser and scans it across film in x-direction.	Spinning polygon w/built-in controller Lenses, mirrors
Transport	Detects and aligns film; moves film through system.	Film sensor Film rollers Stepper motor
Light Collection	Detects transmitted light; performs A/D conversion.	Photodiodes Diffusion screen ADC board
Controller	Provides image data path; generates pixel clock for Light Collection; drives stepper motor for Transport; monitors sensors; controls interface I/O.	Controller board
Software	Code for all Controller functions.	PROM-based firmware
Power Suppl	Provides electrical power for all modules. +5 VDC for digital circuits. ±5 and +24VDC for analog circuits.	5/24V linear supply (2) 5V linear supplies
Enclosure	Provides light-tight, EMI-controlled, clean environment with reasonable user and service access.	Skins Film input slot Film exit bin User interface AC and data cables

2.7

**LD2000 SERIES Specifications**

Light source	Visible semiconductor diode
Spot size	85 - 170 $\mu$ m
Image Detectors	
Type	Solid State
Quantity	Nine
Image Size	
Film Size:	8" to 14" wide
Scan Size:	14.0" x 17.0" min
Pixels Not On Film:	Set to Max OD value
Scan time (14" x 17")	12 seconds typical for 2K resolution
Spatial Resolution	
Number of pixels:	2048 x 2480 1024 x 1240 other pixel resolutions configurable up to 4096 x 4974 on a 14" x 17" film
Pixel Size:	~170 $\mu$ m @ 2048 pixels on 14" ~85 $\mu$ m @ 4096 pixels on 14"
MTF @ 6 lp/mm:	0.4 (85 $\mu$ m pixel at 4096 pixels on 14")
Optical Density	
OD Range:	0.03 to 3.5
OD Resolution	
OD .03 - 2.5:	.01 OD
OD 2.5 - 3.0:	.02 OD
OD 3.0 - 3.5:	.05 OD
Interface	SCSI
(Custom Configurations available per Customer Specifications)	
Grey scale resolution	12 bits (4096)
Power requirements	
Voltage:	87 - 132 / 200 - 264; 4 position user selected
Frequency:	47 - 63 Hz Single Phase
Current Rating:	650 mA

**2.7 LD2000 SERIES Specifications (cont)**

Temperature	
operating	15C to 40C
non-operating	-40C to 60C
Relative Humidity	
operating	25-70% non-condensing
non-operating	10-90%
Dimensions	
with pedestal	11"D x 22.25"W x 48.5" H
wall mount	11"D x 22.25"W x 40" H
Weight	60 – 77 lbs. (with pedestal)

## 2.8 Substantial Equivalence Comparison and Chart

The General Scanning LD2000 SERIES is substantially equivalent to all of the Lumisys, Nishimoto Sangyo and Konica digitizers listed. Specifically,

<i>Size:</i>	The General Scanning model LD2000 SERIES is slightly larger in size than the other products listed. This is primarily due to a stand which is offered with the product.
<i>Weight:</i>	General Scanning's product weight is 60 – 77 lbs. similar to the Lumisys 85LF at 75 lbs.
<i>Power:</i>	All units offer dual voltage (120/240 VAC).
<i>Scan size:</i>	Maximum scan size for all listed digitizers is 14" x 17".
<i>Spot size:</i>	General Scanning's product has an 85µm spot which falls within the 50 - 420µm spot offered by the Lumisys 100.
<i>Density range:</i>	Our density range of 0.03 - 3.5 OD is within the range offered by all products listed.
<i>Grey Scale:</i>	All products listed except Konica offer 12 bit grey scale.
<i>Laser source:</i>	Konica and both Nishimoto Sangyo products use semiconductor laser sources.
<i>Beam scan:</i>	Konica and both Nishimoto Sangyo products use a polygon scanner for scanning the x-axis of the image.
<i>Maximum resolution:</i>	General Scanning's product is exactly equal to the Nishimoto Sangyo ED-3500, and is within the range offered in the Lumisys 85LF.
<i>Interface:</i>	General Scanning is offering a standard SCSI or custom interface. This is equivalent to the products listed.

The following page show a chart highlighting the substantial equivalence of the LD2000 SERIES to the Lumiscan 85LF, Lumiscan100, Konica, Nishimoto Sangyo ED-2000 and ED-3500 Film Digitizer models.



MAR 19 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Steven Zis  
Quality Systems Manager  
General Scanning, Inc. (GSI)  
Optical Scanning Products Division  
500 Arsenal Street  
Watertown, MA 02172

Re: K980565  
LD2000 Series  
Dated: February 12, 1998  
Received: February 13, 1998  
Regulatory class: Unclassified  
Procode: 90 LMA

Dear Mr. Zis:

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

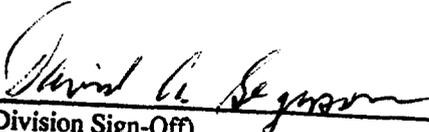
Enclosure

**1.1 Statement of Indications for Use**

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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K980565

Prescription Use   
(Per 21 CFR 801.109)