

OCT 15 1998

510(k) Summary  
as required by 807.92

K982785

## 1. Company Identification

Array Corporation  
3-42-10 Yoyogi, Shibuya-ku, Tokyo 151-0053 Japan  
Tel : +81-3-3320-3911  
Fax : +81-3-3320-5918

## 2. Official Correspondent

Takashi Inami  
Manager  
Quality Engineering Dept.

## 3. Date of Submission

July 22, 1998

## 4. Device Trade name

2905

## 5. Common Name

Laser Film Digitizer

## 6. Classification

Medical image digitizers were reviewed by the Radiology Panel and are classified in Class II per 21 CFR 892.2030.

## 7. Predicate Device

Lumiscan 50, 510(k)# K933129, Lumiscan 20, 510(k)# K953964, manufactured by Lumisys Inc., 225 Humboldt Court, Sunnyvale, California 94089.

## 8. Description of Device

The Laser Film Digitizer 2905 is an image scanner which reads black and white images from transmitted light through an X-ray film and the like, and transfers the images as the digital data to a computer. It has the following features:

- ① Since the 2905 is equipped with a photomultiplier having wide dynamic range as a sensor, it can read high density films, such as a film whose optical density is up to 4.0.
- ② The 2905 can output 4096 gray levels (12 bits) which are linear to optical density.
- ③ The 2905 can read a film at high speed using laser.
- ④ The interface of the 2905 is SCSI-2, so that it can transfer data at high speed.

## 9. Intended Use

The Laser Film Digitizer is intended for reading black and white images from transmitted light through an X-ray film and the like and transferring the images as the digital data to a computer.

## 10. Substantial Equivalence to Predicate Device

The 2905 is substantially equivalent to the Lumiscan 50 (K933129) and Lumiscan 20 (K953964), laser film digitizer manufactured by Lumisys Inc., 225 Humboldt Court, Sunnyvale, California 94089. Comparison of the principal characteristics of the three devices which are pertinent to clinical performance is shown below.

	Array	Lumisys	Lumisys
Product Name	Model 2905	Lumiscan 50	Lumiscan 20
510(k) Number	---	K933129	K953964
Dimensions	526x766x330mm <sup>†</sup>	21x13x27"	21x13x27"
Weight	45kg	75lbs.	75lbs.
Power (V ac/A/Hz)	120/3/50-60	110/1/60	110/1/60
Scan Size	14x17"	14x36"	14x36"
Spot Size	70 $\mu$ m	210 $\mu$ m	175 $\mu$ m
Dynamic Range	0-4.0 OD	0-4.1 OD	0-3.8 OD
Gray Scale	12 bits	12 bits	12 bits
Digitizing Rate	300 lines/sec.	115 lines/sec.	160 lines/sec.
Laser	He-Ne Gas Laser	Laser	Solid State Array
Beam Scan	Polygonal Mirror	Galvanometer	CCD
Pixel per mm	0.5-20	5	5.7
Interface	SCSI	SCSI/PC ISA	SCSI/PC ISA

## 11. Safety Concerns

The Laser Film Digitizer 2905 complies with the following standards (under application for Approvals).

UL1950

CAN/CSA-C22.2 No.950

TÜV:

EN 60950+A1+A2

EN 60825-1

Additionally, the Laser Film Digitizer 2905 complies with CFR 47, Part 15 and Radiation performance standards (21 CFR Chapter I, Sub-chapter J).



OCT 15 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Takashi Inami  
Manager, Quality Engineering Dept.  
Array Corporation  
3-42-10 Yoyogi, Shibuya-Ku  
Tokyo 151-0053, JapanRe: K982785  
2905, Laser Film Digitizer  
Dated: July 28, 1998  
Received: August 7, 1998  
Regulatory class: II  
21 CFR 892.2030/Procode: 90 LMA

Dear Ms. Inami:

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

August 31, 1998

510(k) Number (If known): K982785

Device Name: Laser Film Digitizer 2905

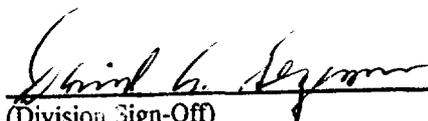
Indications for Use:

The Laser Film Digitizer 2905 is indicated for scanning medical radiographs with a laser beam and generating a digital electrical signal from the transmitted light.

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

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Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K982785

Prescription Use X

OR Over-the-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)