2/12/99

510(k) Summary

K984409

1. Company Identification

Nishimoto Sangyo Co., Ltd.
2-17-4 Yushima
Bunkyo, Tokyo, Japan
Tel. (03) 3818-1324
Fax (03) 3818-1814
e-mail elkint@ca.mbn.or.jb

2. Official Correspondent

Gary J. Allsebrook
Regulatory Affairs

3. Date of Submission

December 7, 1998

4. Device Name

Classification Name:	Medical image digitizers were evaluated by the Radiology panel and are classified in Class II per 21 CFR §892.2040 (proposed).
Common/Usual Name:	Laser Film Digitizer
Proprietary Name:	Elk Laser Film Digitizer, Model ED-3000

5. Substantial Equivalence

Vidar, VXR-LS, Laser Film Digitizer, K974315

6. Device Description and Intended Use

The ED-3000 is a desk top radiographic film digitizer incorporating a laser beam scanned in one direction, a mechanical stage that moves a sheet of film in the orthagonal direction, a light collector and photomutiplier and electronic circuitry for analog-to-digital conversion, system operation and connection to external networks. The intended use of the ED-3000 is to produce digital copies of radiological film.

7. Software

Nishimoto Sangyo Co., Ltd. certifies that the ED-3000 software is designed, developed, tested and validated according to written procedures. These procedures identify individuals within the organization responsible for developing and approving product specifications, coding and testing, validation testing and field maintenance.

8. Hazard Analysis

Hazard analysis on this product has been performed throughout the definition, design, coding and testing phases of product development and implementation. This process has emphasized:

- Identification of potential hazards, their causes, and their effects;
- Development of methodologies to control the occurrence of hazards and to constrain their effects; and
- Determine any effect on patient safety and system effectiveness.

The potential hazards associated with this software product are no different than those of other PACS components . These are primarily related to failure of computer system components, and may be variously obviated by decisions taken by the customers of this product. None of these failures are expected to materially contribute to patient death or injury.

It is our conclusion that there is no hardware or software component, operating in a properly configured environment, whose failure or latent design defect would be expected to result in death or injury of a patient. Thus the "Level of Concern" is "Minor".

9. Safety Concerns

The device was submitted and passed the following tests in accordance with the Standard for Medical Electric Equipment (JIS T 1001, T1002 2nd edition).

10. Substantial Equivalence

The following product provides functions, which are substantially equivalent to this product. Please note that Nishimoto Sangyo is the Original Equipment Manufacturer (OEM) for the Vidar VXR-LS predicate device:

Manufacturer:	**Nishimoto Sangyo**	**Vidar**
Product Name:	Elk Model ED-3000	VXR-LS
510(k) Number:		K974315
Film size:	8"x10" – 14"x17"	8"x10" – 14"x17"
Light Source	Laser Diode (670μm)	Laser Diode
Resolution: (14"x17")		
DPI:	73/146/293	73/146/293
Pixel size (μm):	320/160/80	348/174/87
Pixels:	1024 x 1244/2048 x 2488/4096 x 4976	1022 x 1241/2044 x 2482/4102 x 4981
Density:	8 bit/10 bit/12 bit	8 bit (256) grayscale 12 bit (4096) grayscale
Optical Density:	0~2/0~2.5/0~3/0~3.6	0.0 ~3.6 OD
Scan Rate:	155 lines/sec.	155 Lines/sec.
Interface:	SCSI-2/TWAIN (Win 95)	SCSI-2 conformance

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 1999

Nishimoto Sangyo Co., LTD
Gary J. Allsebrook
Regulatory Management Services
16303 Panoramic Way
San Leandro, CA 94578-1116

Re: K984409
Elk Laser Film Digitizer, Model ED-3000
Dated: December 7, 1998
Received: December 9, 1998
Regulatory class: II
21 CFR 892.2030/Procode: 90 LMA

Dear Mr. Allsebrook:

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 legally marketed predicate 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,

Capt. Daniel G. Schultz, M.D.
Acting 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): K984409

Device Name: Nishimoto Sangyo Co., Ltd. Elk Laser Film Digitizer, Model ED-3000

Indications For Use:

The Model ED-3000 is a desk top laser image digitizer intended to produce digital copies of radiological film.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 901.109) OR Over-the-Counter Use____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K984409