

2974/315

APR 17 1998

**510 (k) Summary
as required by 807.92
for the VXR-LS laser film digitizer
Prepared on November 7, 1997**

Submitted by: VIDAR SYSTEMS CORPORATION
460 Spring Park Place
Herndon, Virginia 20170
Telephone 703 471-7070
Facsimile 703 471-1165

Contact Person: Howard Neal
Medical Business Line Manager.

Device Trade Name: **VXR-LS.**

Common Name: Laser film digitizer.

Classification: Medical image digitizers were reviewed by the Radiology Panel and are classified in Class II per 21 CFR 892.2040 (proposed).

Predicate Device: **Lumiscan 75 (K934496).**

Manufactured by: Lumisys, Inc., 225 Humboldt Court, Sunnyvale, California 94089.

Description of Device:

The Vidar VXR-LS is a digitizer of radiographic film transparencies incorporating a laser beam scanned in one direction, a mechanical stage that moves a sheet of film in the orthogonal direction, a light collector and photomultiplier and electronic circuitry for analog-to-digital conversion, system operation, and connection to external networks.

Intended Use of Device:

The Vidar **VXR-LS Film Digitizer** is intended for producing digital copies of medical x-ray films.

Substantial Equivalence to Predicate Device:

The **VXR-LS** is substantially equivalent to the **Lumiscan 75 (K934496)** laser film digitizer manufactured by Lumisys, Inc., 225 Humboldt Court, Sunnyvale, California 94089. The principal characteristics of the two devices that are pertinent to clinical performance are compared below.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Bill Stamper
Quality Control Manager
Vidar System Corporation
460 Spring Park Place
Herndon, Virginia 20170Re: K974315
VXR-LS Laser Film Digitizer
Dated: March 18, 1998
Received: March 20, 1998
Regulatory class: Unclassified
Procode: 90 LMA

Dear Mr. Stamper:

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

510(k) Number (if known): _____

Device Name: Vidar VXR-LS Film Digitizer

Indications For Use:

The Vidar VXR-LS Film Digitizer is intended for producing digital copies of medical x-ray films.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

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

510(k) Number K974315

Prescription Use Per 21 CFR 801.109)

OR

Over-The-Counter Use _____