

JAN 20 2000

K993598

510 (k) Summary
As required by 807.92
For the MAMMOGRAPHY PRO and Diagnostic PRO-M film digitizers
Prepared on January 17, 2000

Submitted by: VIDAR Systems Corporation
460 Spring Park Place
Herndon, VA 20170
Telephone: (703) 471-7070
Fax: (703) 471-1165

Contact Person: Mary Drinkard
Medical Business Program Manager

Device Trade Name: **MAMMOGRAPHY PRO and Diagnostic PRO-M** x-ray film digitizers.

Common Name: X-ray film digitizer

Classification: Medical image digitizers were reviewed by the Radiology panel and are classified in Class 11 per CFR 892.2040 (proposed).

Predicate Device: MedScan 12 (K933632)

Manufactured by: VIDAR Systems Corporation, 460 Spring Park Place, Herndon, VA 20170

Description of Device: The x-ray film digitizer, an electronic device used to convert analog x-ray films to digital images.

Intended use for the device:
The intended use of the **MAMMOGRAPHY PRO and Diagnostic PRO-M** is to produce digital copies of medical x-ray films.

“The **MAMMOGRAPHY PRO and Diagnostic PRO-M** are indicated for the digitization of mammographic images for review and analysis, but not as the sole basis for screening or diagnosis.”

Substantial Equivalence to Predicate Device:

The **MAMMOGRAPHY PRO and Diagnostic PRO-M** are substantially equivalent to the MedScan 12 (K933632) film digitizer manufactured by VIDAR Systems Corporation, 460 Spring Park Place, Herndon, VA 20170. Technical differences between the devices and the predicate raise no new issues of safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 2000

Mary "Pennie" Drinkard
Medical Business Line Program Manager
Vidar Systems Corporation
460 Spring Park Place
Herndon, VA 20170

Re: K993598
Mammography Pro and Diagnostic
PRO-M
Dated: September 15, 1999
Received: October 25, 1999
Regulatory class: II
21 CFR 892.2030/90 LMA

Dear Ms. Drinkard:

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): K993598

Device Name: MAMMOGRAPHY PRO and Diagnostic PRO-M

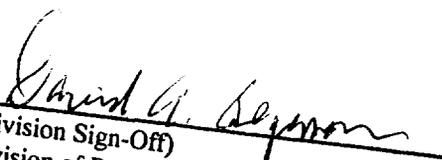
Indications for Use:

The MAMMOGRAPHY PRO and Diagnostic PRO-M film digitizers are intended for converting analog Medical x-ray films to digital images.

The devices are indicated for the digitization of mammography images for review and analysis, but not as the sole basis for screening or diagnosis.

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

Concurrence of CDRH, Office of Devices Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993598

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-the Counter-Use _____