

VEPRO GmbH - An der Tuchbleiche 26 - 64319 Pfungstadt

Document Mail Center (HFZ - 401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard

Rockville, Maryland 20850
USA



Computersysteme

K972215

NOV 19 1997

510(K) SUMMARY

This 510(k) Summary of Safety and Effectiveness information is being submitted in accordance with requirements of SMDA 1990.

The undersigned certifies that the 510(k) Pre-Market Notification for the above referenced product contains adequate information and data to enable CDRH to determine substantial equivalence to Siemens PACS/1-A (k880690). This data is summarized as follows:

1. **MEDImage** has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.
2. The **MEDImage** User's Guide contains comprehensive and extensive information on how to operate the system.
3. This submission contains the results of a hazard analysis.

Submitter:

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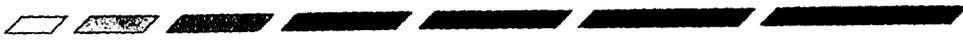
contact person:

Ms. Cissis Cox
VEPRO-Computersysteme GmbH
An der Tuchbleiche 26
D - 64319 Pfungstadt
Germany
tel. (06157) 800 600
fax.(06157) 800 666

Summary Prepared on: 06.. June 1997

Trade name: **MEDImage**

Common name: Picture Archiving and Communications System (PACS)



Computersysteme

Classification name:

No formal classifications have been issued for Picture Archiving, and Communications Systems (PACS) or components, under Section 513 of the Food, Drug, and Cosmetic Act. Images from the VEPRO MEDImage system may be used for primary diagnosis as do other PACS Systems; however, these systems are not represented to be used in supporting or sustaining human life, nor do they present a potential for unreasonable risk of illness or injury. Evaluation of the output is performed by health care professionals and provides adequate opportunity for competent human intervention. Therefore, we believe that all digital archives meet the requirements of a Class I Device.

VEPRO claims Substantial Equivalence to: Siemens PACS/I-A (K880690)

Device Description:

MEDImage is a software package designed to acquire analogue and digital images from any modality, store and archive these images together with patient information on hard disk and/or on long-term media such as standard optical disks; search for and retrieve these images for re-consultation, processing and/or transmission. **MEDImage** utilizes industry standard equipment.

Intended Use:

MEDImage will be used to acquire, display, process, archive, retrieve, and transmit diagnostic radiological images and information about these images in a single user or network environment. Typical users of **MEDImage** are trained medical professionals.



Food and Drug Administration
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Rockville MD 20850

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Cissie Cox .
Sales Support
Vepro Computersysteme GMBH
An der Tuchbleiche 26
D-64319 Pfungstadt, Germany

Re: K972215
Medimage
Dated: September 26, 1997
Received: October 2, 1997
Regulatory class: Unclassified
Procode: 90 LLZ

Dear Ms. Cox:

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 requirement, 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/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

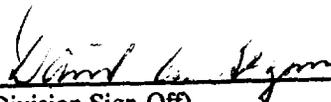
3 INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: MEDImage

Indications For Use:

MEDImage will be used to acquire, display, process, archive, retrieve, and transmit diagnostic medical images and information about these images in a single user or network environment. The typical users are trained medical professionals.



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972215

Prescription Use _____
(Per 21 CFR 801.109)