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K971776

JUL 14 1997

Section 5

5. 510(k) Summary

Submitter

Douglas Seaborn
Chief Executive Officer
VMI Technologies
412-126 York Street
Ottawa, Ontario
Canada
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Telephone: (613) 241-4040 x22
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Device Name

Trade name: EchoVACS™

Common name: Picture archiving and communications system (PACS)
(ultrasound)

Classification name: Picture archiving and communications system (PACS)

Intended Use

EchoVACS™ is indicated for the capture, archiving, retrieval and display of echocardiography images. It permits annotation of images as well as recording and analysis of workload statistics. It also permits report generation from a comprehensive internal lexicon of anatomic and diagnostic terms covering adult, pediatric and fetal echocardiography.

Device Description

EchoVACS™ is an all-digital networked system that is intended to give the echocardiography department a solution for the capture, storage, retrieval and reporting of full-length echocardiograms. EchoVACS™ consists of three modules:

- Capture station – this is connected to the ultrasound machine and acquires the patient's echo exam. The images are compressed using MPEG (Moving Pictures Expert Group) which is an ISO standard (ISO/IEC 11172). Once captured, the exam is available to any station on the network.
- Review station – this is connected to the network and is used to both view echo exams and to generate the physician's report.
- Database server – this supports the Capture and Review stations by providing centralized functionality such as the storage of patient demographics.

EchoVACS™ is substantially equivalent to the ALI UltraPACS system (K963610).

Comparisons to Predicate Device

The user features of EchoVACS™ and ALI UltraPACS system (K963610) are very similar.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Doug Seaborn
Chief Executive Officer
VMI Technologies, Inc.
412-126 York Street
Ottawa, Ontario
Canada K1N 5T5

Re: K971776
EchoVacs™ (Picture Archiving
and Communications Systems (PACS))
Dated: May 9, 1997
Received: May 13, 1997
Regulatory class: Unclassified
Procode: 90 LLZ

JUL 14 1997

Dear Mr. Seaborn:

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/dsmmain.htm>.

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) K971776

Device Name: ECHOVACS

Indications For Use:

EchoVACS™ is indicated for the capture, archiving, retrieval and display of echocardiography images. It permits annotation of images as well as recording and analysis of workload statistics. It also permits report generation from a comprehensive internal lexicon of anatomic and diagnostic terms covering adult, pediatric and fetal echocardiography.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rita Phelps
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971776

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)