

510(k) Summary

**Date prepared:** June 30, 1999  
**Name of contact person:** Robert Kriedermann  
**Device trade name:** Echocardiography System  
**Common name:** Echocardiography System  
**Classification name:** Picture Archiving and Communications System  
**Predicate substantially equivalent devices:** K980060 MPACS, LLC "EchoLINK"

**Device description and intended use:** The Echocardiography System provides a digital image transport and archive solution for hospitals wishing to replace their current VCR-based system. Currently, a typical cardiac echo department operates by manually shuttling VCR tapes between echo machines and VCR players. The Echocardiography System provides a high-speed digital link between these nodes. It also supports digital archival of echo exams in order to eliminate the cost and inconvenience of permanent storage via VCR tapes.

**Predicate device specifications comparison:**

	<i>Principal Device</i> <b>Camtronics Echocardiography System</b>	<i>Predicate Device</i> <b>MPACS "EchoLINK" K980060</b>
<b>Image Acquisition Unit</b>		
Compression type and ratio	JPEG, up to 30:1	MPEG2 up to 55:1
Video source	RGB, YC, or composite input	S-Video or Composite, NTSC or PAL
Computer/operating system	Pentium II/Windows NT4.0	Pentium II, 350 MH/Windows NT4.0
User interface	User multifunction remote control, and mini-remote	Keypad and trackball
<b>Review Station</b>		
Image storage media	Internal hard disk, CD-R	Internal hard disk, removable 3.5" magneto-optical disk
Display	17", 19", or 21" color monitors, up to 1024x1024 24 bit depth	21" color monitor, 1024x768, 24 bit color depth
Computer/operating system	Pentium II, 400 MHz/windows NT 4.0	Pentium II, 350 MHz/Windows NT4.0
User interface	Keyboard, mouse, and rotary playback control	Keyboard and mouse
<b>Image Server</b>		
Media	CD-R, or DLT tape, or others as available	100 CD-R
Storage capacity	up to 2 weeks of studies on-line, and approx 1 year near-line	20 minutes per CD-R at 4Mb/s MPEG2
<b>Network</b>		
Type	Fast Ethernet	Fast Ethernet
DICOM	Yes	Yes

**Performance data:** Not required for determination of substantial equivalence for this class of device.

**Conclusions drawn from clinical and nonclinical test data:** Not required for determination of substantial equivalence for this class of device.

**Substantial equivalence summary:** The Camtronics Echocardiography System is a comparable type and substantially equivalent to a legally marketed predicate device. The intended use of the Camtronics Echocardiography System is the same as that of the predicate device "EchoLINK" marketed by MPACS, LLC. No new safety or effectiveness issues are raised with the Camtronics Echocardiography System. The subject device has substantially equivalent technological characteristics, features, specifications, materials, modes of operation, and intended uses as a legally marketed predicate device.

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SEP 8 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Robert Kriedermann  
Regulatory Specialist  
Camtronics, Ltd.  
900 Walnut Ridge Drive  
P.O. Box 950  
Hartland, Wisconsin 53029

Re: K992259  
Camtronics Echocardiography System  
Dated: June 30, 1999  
Received: July 6, 1999  
Regulatory Class: II  
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Kriedermann:

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): K992259

DEVICE NAME: Echocardiography System

INDICATIONS FOR USE:

A digital image capture, storage, and review system for echocardiography.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)

*David A. Szymon*  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K992259