2/19/99

INNOVATIVE MEDICAL SOLUTIONS
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1250 Newport Drive
Oconomowoc, WI 53066

K990052

9.0 510(k) Summary

Submitter

Innovative Medical Solutions
1250 Newport Drive
Oconomowoc, WI 53066

Contact

Lawrence E. Sieb, Jr.
Tel: 414-569-5716
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Device Name

Classification: Unclassified
Common/usual name: Tele-echocardiography system, a PACS (Picture Archive and Communications) device
Proprietary Name: Tel-Echo System

Intended Use

The Tel-Echo System is intended to acquire echocardiographic images during a cardiac ultrasound exam and transfer them to another location for viewing. This system is intended for tele-echocardiography applications.

Device Description

The Tel-Echo System is designed specifically to transmit cardiac ultrasound (echocardiographic) exams over telephone lines for remote review. This application is usually referred to as tele-echocardiography.

A Tel-Echo System may send complete exams from a remote clinic to the main clinic. It may also send selected images to a physician's home or office for "on call" coverage. The Tel-Echo System acquires echocardiographic images in parallel with the VCR(Video Cassette Recorder) or other recording method. This VCR tape or equivalent digital media comprise the exam record and not the Tel-Echo system, which is for communication only.

Comparisons to Predicate Device

The substantial equivalent devices are: the Network Concepts, Inc. Univision System, FDA 510K Number K964803; VMI Technologies EchoVacs product, FDA 510K Number K971776; and the MPACS EchoLink product, FDA 510K Number K980060.

In reviewing the comparison between Innovative Medical's Tel-Echo system and the predicate devices, two differences are noted. One is that the Innovative Medical system and the MPACS system offer a choice of MPEG compression ratios while the Network Concepts and the VMI Technologies systems only offer one. The use of different compression ratios allows the user to match the speed of the data transfer with the bandwidth of different types of telecommunications line.

The other difference between the predicate devices and the Innovative Medical Tel-Echo system is that the predicate devices all offer an archive capability to replace the video cassette currently employed for archive. The Innovative Medical Solutions system does not offer archive capability and relies upon the user keeping the current medical record whether that be a video cassette or other media.

Conclusion

All of the predicate devices and Innovative Medical Solutions' Tel-Echo system are intended for use in an echocardiography laboratory. All of the predicate devices and the Innovative Medical Solutions' Tel-Echo system use similar technology to acquire exams for subsequent review over a wide area network and use MPEG standard compression. Thus, for tele-echocardiography, the Innovative Medical Solutions' device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1999

Lawrence E. Sieb, Jr.
President
Innovative Medical Solutions
1250 Newport Drive
Oconomowoc, WI 53066

Re: K990052
Tel-Echo System
Dated: January 6, 1999
Received: January 7, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Sieb:

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): K990052

DEVICE NAME: Tel-Echo System

INDICATIONS FOR USE:

The Tel-Echo System is intended to acquire echocardiographic images during a cardiac ultrasound exam and transfer them to another location for viewing. This system is intended for tele-echocardiography applications.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990052