



K980060

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Middleton, WI 53562-4100  
(608) 798-1111

**510(K) SUMMARY**  
**(As Required by 21 CFR 807.92(c))**

FEB 25 1998

**A. Submitter's Name and Address**

MPACS, LLC  
4828 Enchanted Valley Road  
Middleton, WI 53562-4100

Phone: (608) 798-1111  
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**B. Contact Person**

Dennis D. Roscoe, Ph.D.  
Phone: (608) 798-1111  
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**C. Date of Submission:** January 5, 1998

**D. Device Name**

**D.1. Device Trade or Proprietary name:** EchoLINK™.

**D.2. Device Common or Usual Name:** Picture Archiving and Communications Systems (PACS)

**D.3. Classifications:** Image Processing System

**D.4. Product Code:** 92LLZ

**D.5. Class:** Unclassified (Accessory to a Class II ultrasound parent device)

**D.6. Classification Panel:** Radiology

## **E. Equivalent Devices**

The equivalent legally marketed devices are the UNIVISION system (510(k) Number K964803) manufactured by NCI (Network Concepts, Inc.) for routine echocardiography and the TomTec<sup>P90</sup> (510(k) Number K950279) manufactured by TomTec Imaging Systems, Inc. for stress echocardiography.

## **F. Device Description**

EchoLINK provides a telecardiology system, a complete image management system, and a stress echo acquisition and measurement system. There are four major components that make up the EchoLINK device; an image acquisition unit, a review station, a CDR library system, and the networking components.

The EchoLINK image acquisition unit (IAU) uses MPEG2 technology to convert analog video coming from the ultrasound machine to digital video in real time. The IAU can store up to 130 minutes of digital video data on its internal hard disk or 20 minutes on a removal digital storage device. The data storage format is in standard WindowsNT or DICOM 3. The IAU employs user-defined protocols for view indexing. The IAU allows for the placement of time markers within a view to identify the start and end of systole (necessary for stress echo applications) and allows the user to measure left ventricular function. The IAU is network-ready for transferring patient data to a central CDR library system and/or to a physician's review station. The EchoLINK device has an electronic report generator that allows the sonographer and physician to enter exam information as part of a paperless reporting system.

The EchoLINK device, when equipped with an optional modem or ISDN interface, can be remotely accessed to provide a variety of telecardiology solutions. The device is controlled by MPACS proprietary software.

## **G. Intended Use**

This device is intended for use by health care professionals trained in the field of echocardiography or medical ultrasound. It is to be used when there is a need to convert ultrasound analog video to a digital video format for subsequent review and archiving. This device is also intended for use in transferring ultrasound images over digital networks and/or digital communication lines.

## **H. Substantial Equivalency Comparison**

There are some technological differences between the EchoLINK device and the equivalent devices, however these differences do not affect the safety or effectiveness of the new device. These differences are discussed below.

With respect to routine echocardiography and image management, EchoLINK is substantially equivalent to the UNIVISION product except for the level of MPEG

compression used. UNIVISION uses MPEG1 compression, which limits the image size to 352x240, and only digitizes the even field within a video frame. Only digitizing one field causes a softening of the image (less defined edges). MPEG2 employs a larger image size, 352x480, which doubles the horizontal resolution of the image. MPEG2 also digitizes both the even and odd fields of the video frame for a much sharper image. Finally, EchoLINK uses MPEG2 compression for routine studies because of the current efforts by the ACR/NEMA DICOM standards committee to include MPEG2 into the DICOM standard. EchoLINK only uses MPEG1 for non-diagnostic telecardiology applications.

With respect to stress echo applications, EchoLINK is substantially equivalent to the TomTec<sup>P90</sup> product except for the type of video compression used. EchoLINK's image acquisition unit records streaming video (continuous video segments for a duration determined by the user) as oppose to image clips for a duration set by the acquisition unit. The TomTec<sup>P90</sup>, employs the use of image clips compressed by motion JPEG technology. JPEG can only achieve usable compression ratios up to 20 to 1. Therefore, in order to limit the storage requirements, the TomTec<sup>P90</sup> limits acquisition times to a few seconds or less per view of the heart. This technique of limiting acquisition times is called "Clinical Compression". Additionally, JPEG does not allow for the digitizing of audio, which is an important component that needs to be recorded during Doppler examinations. The MPEG2 compression technique, which is an international standard for full-motion video compression and covered under the equivalent NCI UNIVISION device (K964803), used by EchoLINK provides 55:1 compression and records full stereo sound. There is no need for clinical compression with the EchoLINK device and image acquisitions can be the same duration as previously used with VCR tape storage.

One additional minor technology difference between EchoLINK and the TomTec<sup>P90</sup> is how the devices mark a particular portion of a view for display. In most stress echo protocols, only the contraction phase (systole) of the cardiac cycle is of interest. In the TomTec<sup>P90</sup>, this limit duration view is acquired by triggering acquisition off the R-wave portion of the ECG and collecting a fixed number of frames. It is critical that the sonographer selects the correct number of post-triggered frames in order to properly capture the systolic event. The number of frames selected will depend on the patient's heart rate. You need more frames when the heart is at rest than when the heart is at peak stress. Selecting an inappropriate number of frames, post R-wave, is a potential source of error. To eliminate this potential source of error, EchoLINK's image acquisition unit allows the sonographer to collect multiple cardiac cycles and then while reviewing the images place markers within the view to precisely mark the beginning and end of systole. This eliminates the trial and error approach of triggering on the R-wave and increases the effectiveness of the new device.

EchoLINK's performance is the same as the equivalent marketed devices. All three devices are required to acquire and digitize full-motion (30 frames per second) analog video in real time. Likewise all three devices can playback the stored digital video in real-time.

## **I. Conclusions**

EchoLINK, NCI's UNIVISION, and the TomTec<sup>P90</sup> are all used in the same way to digitally acquire, store and review ultrasound exams. All three devices interface with the ultrasound machine in a similar manner via the machine's analog video output.

There are some technological differences between the new device and the equivalent devices, however these differences do not affect the safety or effectiveness of the new device.

Based on the intended use and the comparisons between the EchoLINK device and the legally marketed devices, there are all the indications that the EchoLINK device is substantially equivalent to the NCI's UNIVISION and the TomTec<sup>P90</sup> devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 25 1998

Dennis D. Roscoe, Ph.D.  
Managing Member  
MPACS, LLC  
4828 Enchanted Valley Road  
Middleton, Wisconsin 53562

Re: K980060  
EchoLINK (Picture Archiving and  
Communications Systems  
Dated: January 5, 1998  
Received: January 7, 1998  
Regulatory class: Unclassified  
Procode: 90 LLZ

Dear Dr. Roscoe:

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 (Pre-market 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,

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): \_\_\_\_\_

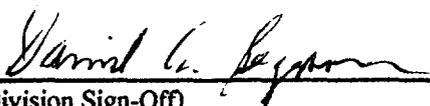
Device Name: EchoLINK

**Indications For Use:**

This device is intended for use by health care professionals trained in the field of echocardiography or medical ultrasound. It is to be used when there is a need to convert ultrasound analog video to a digital video format for subsequent review and archiving. This device is also intended for use in transferring ultrasound images over digital networks and/or digital communication lines.

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K980060

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_