MPACS
THE POWER OF INTEGRATION

K030242

7601 Ganser Way
Madison, WI 53719
(608) 827-7111

MAR 1 0 2003

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

A. Submitter's Name and Address

MPACS, LLC
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Madison, WI 53719

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B. Contact Person

Greg Sopotnick
Phone: (608) 827-7111
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C. Date of Submission: January 21, 2003

D. Device Name

D.1. Device Trade or Proprietary name: fyreLINK™.

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

D.3. Classifications: Image Processing System

D.4. Product Code: LLZ

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 echoLINK system (510(k) Number K980060) manufactured by MPACS and the EnConcert system (510(k) Number K954668) manufactured by Philips Medical Systems for routine echocardiography and the TomTec^{P90} (510(k) Number K950279) manufactured by TomTec Imaging Systems, Inc. for stress echocardiography.

F. Device Description

fyreLINK (formerly echoLINK) now provides the cardiology ultrasound market a real-time solution for dealing with EC data, a telecardiology system, a complete image management system, and stress echo acquisition with LV function, M-mode, and Doppler measurements. There are four major components that make up the fyreLINK product line; an image acquisition unit, a review station, a DVD library system, and the networking configuration. The telecardiology system uses the same components except for the DVD library system. Appendix D shows several examples of how these components can be arranged to provide customer solutions.

The fyreLINK image acquisition unit (IAU) is the key component of the fyreLINK device. It uses a hardware video converter to convert analog video coming from the ultrasound machine to streaming digital video in real time. This streaming digital video can then be compressed using MPEG 2 or a lossless compression technique (run-length encoding), and stored on the local hard drive as an MPEG2 or an AVI file. The IAU can store up to 1000 minutes of digital video data on its internal hard disk if MPEG2 compression is used, or 30 minutes if lossless compression is used.. The data is available for immediate review on the IAU, or can be exported to another application or another workstation or archive. The IAU employs user-defined protocols for view indexing. Each acquired view is an individual file. The IAU allows the user to place time markers within a view to identify the start of systole (the contraction phase of the heart). This intra-view marking is necessary for stress echo applications. The IAU is built on a Windows 2000 platform, and is network-ready for transferring patient data to a local or central archive system and/or to a physician's review station. The IAU's compact size allows it to be a direct replacement for the ultrasound machine's existing VCR. The IAU platform can consist of either a laptop or desktop type computer. The device has an electronic report generator that will allow the sonographer and physician to enter exam information as part of a paperless reporting system. The IAU, when configured as part of a WAN environment, can be a part of a remote access telecardiology system. The IAU is controlled by MPACS proprietary software.

fyreLINK offers two review station solutions. Acquired images can be reviewed at the IAU, or the image files can be exported for use with another application. THE REVIEW FUNCTION OF FYRELINK SOFTWARE LABELS ALL RECALLED IMAGES WITH THE TYPE OF COMPRESSION USED AND THE COMPRESSION RATIO.

fyreLINK used in a network environment can integrate with a mass archive solution already in place. As an alternative, the IAU includes a CD-R recorder built in, to permit immediate local archival of ultrasound studies. CD-R recorders can also be added to customer review stations.

MPACS will supply network solutions for integrating the fyreLINK components. In a network configuration, the image acquisition unit moves patient studies directly to a server. The review station is able to review both on-line and near-line studies. Network solutions will also include telecommunication links such as T1, ISDN, and modem connections for telecardiology.

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 images 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 fyreLINK device and the equivalent devices, however these differences do not affect the safety or effectiveness of this device. These differences are discussed below.

With respect to routine echocardiography and image management, fyreLINK is substantially equivalent to the echoLINK product. In fact, fyreLINK is essentially the echoLINK product with the additional option of run-length encoding (RLE) lossless compression used in creating AVI files. fyreLINK still produces the same MPEG2 files that echoLINK does and can export still images in a BMP format. The EnConcert system uses lossless RLE compression and can export AVI files. EnConcert also exports still images in BMP format.

With respect to stress echo applications, fyreLINK is substantially equivalent to the TomTec^{P90} product except for the type of video compression used. fyreLINK'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^{P90}, employs the use of image clips compressed by JPEG technology. JPEG typically uses compression ratios up to 20 to 1. Therefore, in order to limit the storage requirements, the TomTec^{P90} 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 is an international standard for full-motion video compression and is covered under the equivalent MPACS echoLINK device (K964803). This technology

used by fyreLINK provides 44:1 compression and records full stereo sound. There is no need for clinical compression with the fyreLINK device and image acquisitions can be the same duration as previously used with VCR tape storage.

One additional minor technology difference between fyreLINK and the TomTec^{P90} 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^{P90}, 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, fyreLINK'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 this device.

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

I. Conclusions

fyreLINK, echoLINK, Philips EnConcert, and the TomTec^{P90} are all used in the same way to digitally acquire, store and review ultrasound exams.

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

Based on the intended use and the comparisons between the fyreLINK device and the legally marketed devices, there are all the indications that the fyreLINK device is substantially equivalent to the echoLINK, Philips EnConcert, and the TomTec^{P90} devices.

(End of 510(k) Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 0 2003

Mr. Greg Sopotnick
Quality Assurance Manager
MPACS
7601 Granser Way
MADISON WI 53719

Re: K030242
Trade/Device Name: fyreLINK
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LZZ
Dated: January 21, 2003
Received: January 23, 2003

Dear Mr. Sopotnick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K030242

Device Name: fyreLINK

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 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Prescription Use ✓

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Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030242