K03 2324

OCT - 2 2003

510(k) Summary

Date prepared:	7/1/03	
Name of contact person:	James P. Loehr, M.D. Icardiogram, Incorporated 100 East Six Forks Road Suite 305 Raleigh, NC 27609 919-534-2150 (telephone) 919-534-2168 (fax)	
Device trade name:	Echoencoder	
Common Name:	Echocardiogram encoding and transfer software system	
Classification Name:	Class II	
	892.2031	Medical image digitizer
	892.2050	Picture archiving and communications system
Predicate substantially equivalent devices:		
	K990052	Tel-Echo System
	K980060	EchoLINK

Device description:

Echoencoder is a combined software-hardware system that is composed of three parts: 1) a system for conversion of analog echocardiographic video to a Quicktime movie file format, and subsequent automated transfer of that file to an Internet server; 2) a system for conversion of digital echocardiographic video to a Quicktime movie file format, and subsequent automated transfer of that file to an Internet server; and 3) an optional Server based database system for tracking of interpretations of the video so obtained.

The system for analog video conversion is composed of a Macintosh computer equipped with the echoencoder software, and a video cassette recording device equipped with a video digitizer. The cassette recorder is interfaced with the computer via a firewire cable. The operator inserts a video cassette into the video cassette recorder, and uses the software program to convert the video into a Quicktime movie, perform MPEG-4 based video compression to compress the file by approximately 50:1, and transfer the file to a server where it can be subsequently reviewed by a Cardiologist.

The system for digital video conversion is also composed of a Macintosh computer equipped with the echoencoder software, and is interfaced with a health care provider's network server. The operator selects the file to be converted, generally in DICOM format, and the software subsequently converts the video into a Quicktime movie, performs MPEG-4 based video compression to compress the file by approximately 25:1, and transfers the file to a server where it can be subsequently reviewed by a Cardiologist.

The server based database product is, by the customer's option, interfaced with the above described Echoencoder system. This system that is based on the software product Filemaker Pro, and allows for electronic report generation and review.

Intended Use

The device is intended to be used by health care professionals in the field of echocardiography. It is anticipated that it will be used when echocardiograms must be performed in a location where no interpreting cardiologist is present, and will facilitate prompt interpretation of echocardiograms. The device is capable of transferring ultrasound images over long distances as digital files.

Substantial Equivalency Comparison

There are technological differences between Echoencoder and the equivalent devices, but these differences do not alter the effectiveness or safety of the new device.

Echoencoder is substantially equivalent to the EchoLINK device in that both provide for conversion of analog data to a digital format. The EchoLINK device uses MPEG-2 video compression at a ratio of 55:1, and provides full audio sound; depending on the source video, Echoencoder uses a compression ratio of between 20:1 and 50:1. Echoencoder uses a MPEG-4 compression method, which allows for a wide range of final data transmission speeds, resulting in the creation of a Quicktime movie which can be viewed full-screen by a free viewer on any computer platform. Both products provide a method for remote viewing of echocardiograms, and both provide a method of report generation. The Echoencoder method produces an image which is 640 x 480 pixels instead of 325 x 245 for MPACS.

The Tel-Echo system is also designed for remote echocardiography interpretation and uses MPEG compression. It differs from Echoencoder in the type of MPEG used, and sends the video to an Internet server as opposed to transfer directly to an interpreting cardiologist by the Tel-Echo system.

Conclusion

Echoencoder, EchoLINK, and Tel-Echo are all used for the same purpose, to convert echocardiographic video into digital files for transfer over communications lines. All use compression techniques that are comparable in degree, and all use MPEG, although the Echoencoder technique is unique in that it uses MPEG-4 and can be viewed using a free video player (Quicktime).

Based on the intended use and comparisons with legally marketed devices noted here, Echoencoder is substantially equivalent, safe, and at least as effective as the EchoLINK and Tel-Echo products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

James Loehr, M.D.
President
Icardiogram, Inc.
100 East Six Forks Road, Ste. 305
RALEIGH NC 27609

Re: K032324
Trade/Device Name: Echoencoder
Regulation Number: 21 CFR §892.2030
Regulation Name: Medical image digitizer
Regulation Number: 21 CFR §892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 1, 2003
Received: July 30, 2003

Dear Dr. Loehr:

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

K03 2324

INDICATION FOR USE

Applicant: Icardiogram, Incorporated

510(k) Number: Applied for

Device name: Echoencoder

Indication for Use:

The device is intended to be used by health care professionals in the field of echocardiography. The device is capable of transferring ultrasound images over long distances as digital files. It is used to transmit echocardiograms over the Internet for the purpose of interpretation of echocardiograms at a remote location. It is anticipated that it will be used when echocardiograms must be performed in a location where no interpreting cardiologist is present, and will facilitate prompt interpretation of echocardiograms. It should be particularly useful in rural areas of the United States.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 1 OR Over-the-Counter _____
Per 21 CFR 801.109 (Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032324