JUL 16 2004

510(K) Summary

This is a summary of 510(k) safety and effectiveness information is being submitted in accordance with the SMDA 1990 and 21 CFR 807.92.

DATE:

5 April 2004

SUBMITTER:

Heartlab Inc.
One Crosswind Road
Westerly, RI 02891
Phone: (401) 596-0592
Fax: (401) 596-8562

CONTACT PERSON:

Richard Petrocelli
Tel No: (401) 596-0592

IDENTIFICATION OF THE PRODUCT

TRADE NAME:	Encompass™
COMMON NAME:	Cardiac Network
CLASSIFICATION NAME:	Image Processing System, LLZ

SUBSTANTIAL EQUIVALENCE INFORMATION:

Encompass is considered comparable and substantially equivalent to the following predicate devices currently in commercial distribution:

Model	**Manufacturer**
Impax (k022292)	Agfa Corp.
EchoNet (k954860)	Lockheed Martin
Inturis Suite (k994210)	Philips Medical Systems

DEVICE DESCRIPTION:

Encompass™ is a picture archiving and communications system intended to be used as a networked cardiovascular information management system. Encompass™ is software comprised of modular software programs that run on standard "off-the-shelf" personal computers and servers running the Windows 2000/XP operating system. Encompass™ is image data storage and display software that accepts DICOM (Digital Imaging and Communications in Medicine) data from laboratories, which support DICOM standard imaging transfer. The system provides the capability to; consolidate images generated by equipment from multiple OEM vendors, view images, enter clinical findings while viewing the associated images, perform digital subtraction, create graphical representation of coronary arteries, perform quantitative measurements on both cath and ultrasound images, perform quantitative analysis on cath images, generate and review patient reports with additional measurement and report writer capabilities and provides accessible digital image archive. Encompass™ is a scalable network system designed to service customers ranging in size from small departments (with 2 or 3 users) to large hospital networks (with tens of users). The original core functionality is detailed below:

1. Review of x-ray angiography, ultrasound, intravascular ultrasound, computed tomography (CT), nuclear medicine, and magnetic resonance imaging (MRI) images.
2. Compare images from different studies on one or two monitors, regardless of modality.
3. Perform report data entry and view the report.
4. Print, save as mpeg/avi, save as bitmap, and copy to clipboard any image(s).
5. Perform standard image processing such as brightness, contrast, gamma, sharpen, window/level, invert, pan, zoom, and digital subtraction.
6. Perform standard stop, start, single frame advance and reverse, previous/next image playback, and various standard clinical presentations.
7. Control the speed of playback.
8. Use a supported jog wheel to control playback.
9. Play/repeat a subset of a loop with user defined begin and endpoints.
10. Search sources for studies based on demographic information.
11. Copy any study or subset of study from any supported source to any supported destination.
12. Write DICOM study to CD/DVD for interchange.
13. Calibrate the monitor to a SMPTE pattern.

DESCRIPTION OF CHANGE OR MODIFICATION:

Encompass™ has been modified to permit the following software functionality:

1. Create graphical representation of coronary and vascular arteries.
2. Perform quantitative measurements on clinical images, and store the results in the database.
3. Perform quantitative analysis on cath images and store the results in the database.
4. Perform optical character recognition of echo measurements from ultrasound images and store the results in the database.
5. Supports the HIPAA directives by allowing capabilities with regards to patient data security, access and privacy concerns.

INTENDED USE:

The intent of this device is to provide diagnostic quality image review, image archive, analysis and measurement capabilities, and findings report generation and report review capabilities. Encompass™ is indicated for use by the physician to aid in diagnosis, and by medical professionals whenever they would require or desire access to medical images and patient demographic information.

STANDARDS:

Encompass™ is designed in accordance with product safety and performance requirements set forth in the following standards:

1. Digital Imaging and Communications in Medicine (DICOM)
2. 21 CFR 1020.10 Video Monitor Performance Requirements
3. 21 CFR 1040.10 Fiber optic communications Performance
4. Society of Motion Picture and Television Engineers (SMPTE)
5. ACR/NEMA Data Compression Standard
6. Underwriters Laboratories (U.L.) Standard No. 544 for Medical and Dental Equipment
7. ISO/IEC 10918-1 Digital Compression and Coding Continuous-Tone Still Images (JPEG)

SUMMARY OF DESIGN CONTROL ACTIVITIES:

The risk analysis used to assess the impact of the modifications was based upon the previous risk analysis and incorporated the software modifications indicated in this submission.

The following quality assurance design control measures were applied to the development of the Encompass™ product:

1. Risk Analysis
2. Requirement Reviews
3. Design Reviews
4. Testing on unit level (Module verification)
5. Integration testing (System verification)
6. Final acceptance testing (Validation)
7. Performance testing

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The modifications to the Encompass™ product do not affect the intended use or alter the fundamental scientific technology of the device. The only device modification was to software. There are no labeling changes that affect the intended use of the device. The device modifications raise no new issues of safety or effectiveness.

All products operate on commercially available computer systems.

All comply with DICOM standard for communications with other imaging system components.

DECLARATION OF CONFORMITY (807.87(g) / 21 CFR 820.30)

All verification and validation activities were performed by the designated individual(s), and the results demonstrated that the predetermined acceptance criteria were met.

Daniel M. Reifsteck

Signature

Daniel Reifsteck, VP of Engineering Operations

Typed Name

4-5-2004

Dated

The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30, and the records are available for review.

Lori Kahler

Signature

Lori Kahler, Quality Assurance Manager

Typed Name

4-5-2004

Dated

CONCLUSIONS:

The principles of operation of the Encompass system are substantially equivalent to the currently marketed products. This system poses no added risk to safety.

This concludes this Special 510(k): Device Modification (k003562).

Richard Petrocelli,
President
Heartlab, Inc

Attachment: Indications For Use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2004

Ms. Lori Kahler
Quality Assurance Manager
Heartlab Cardiac Solutions
One Crosswind Road
WESTERLY RI 02891

Re: K040896
Trade/Device Name: Encompass™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: May 14, 2004
Received: May 17, 2004

Dear Ms. Kahler:

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 such 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

Heartlab
CARDIAC SOLUTIONS

Attachment

510(k) Number: K040891
Device Name: Encompass™

Indications For Use:

Encompass™ is a picture archiving and communications system intended to be used as a networked cardiovascular information management system. Encompass™ is software comprised of modular software programs that run on standard "off-the-shelf" personal computers and servers running the Windows 2000/XP operating system. Encompass™ is image data storage and display software that accepts DICOM (Digital Imaging and Communications in Medicine) data from laboratories, which support DICOM standard imaging transfer. The system provides the capability to; consolidate images generated by equipment from multiple OEM vendors, view images, enter clinical findings while viewing the associated images, perform digital subtraction, create graphical representation of coronary arteries, perform quantitative measurements on both cath and ultrasound images, perform quantitative analysis on cath images, generate and review patient reports with additional measurement and report writer capabilities and provides accessible digital image archive. Encompass™ is a scalable network system designed to service customers ranging in size from small departments (with 2 or 3 users) to large hospital networks (with tens of users).

Prescription Use ✓

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040896

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