FEB 1 8 2005

K050718

Special 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:

31 January 2005

SUBMITTER:

Heartlab Inc.
One Crosswind Road
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Phone: (401) 596-0592
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CONTACT PERSON:

Richard Petrocelli
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IDENTIFICATION OF THE PRODUCT

TRADE NAME:	Ascentia™
COMMON NAME:	Encompass Cardiac Network
CLASSIFICATION NAME:	Image Processing System, LLZ CFR 892.2050

SUBSTANTIAL EQUIVALENCE INFORMATION

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

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

Predicate Technical Characteristics

Feature	Heartlab, Inc. Ascentia (formally Encompass)	Agfa Corp. Impax	Philips Inturis Suite
Operating System	Windows NT / 2000 / 2003 / XP	Windows NT	Windows NT
Image Source	DICOM	DICOM	DICOM
Display Rate	Over 30 fps	Up to 30 fps	Up to 30 fps
Multiple Windows	Yes	Yes	Yes
Image Export	bmp, jpg, mpg	bmp, jpg, mpg	bmp, jpg, avi
Network Access	Yes	Yes	Yes
Analysis	Yes	Yes	Yes
Reporting	Yes	Yes	Yes

Very little difference can be found between Heartlab, Inc. Ascentia™ and the predicate devices noted above. Both systems take DICOM images from DICOM compliant imaging systems. Both systems archive this data in the DICOM format and provide a retrieval function for review, analysis and reporting.

For the acquisition of images from DICOM compliant imaging systems and the conversion of these images for distribution over a network; the Heartlab, Inc. system, and both the Agfa and Philips systems use similar techniques and offer the same functionality. Thus, for DICOM compliant image distribution over a network, the Heartlab, Inc. Ascentia™ device is substantially equivalent to the predicate devices noted above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Mr. Richard Petrocelli
President
Heartlab Cardiac Solutions
One Crosswind Road
WESTERLY RI 02891

Re: K050228
Trade/Device Name: Ascentia®
(formally Encompass®)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and
Communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: January 31, 2005
Received: February 1, 2005

Dear Mr. Petrocelli:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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 A

510(k) Number: K050228
Device Name: Ascentia™ (formally Encompass™)

Indications For Use:

Ascentia ™ (formally Encompass™) is a picture archiving and communications system intended to be used as a networked cardiovascular information management system. Ascentia™ is software comprised of modular software programs that run on standard "off-the-shelf" personal computers and servers running the Windows 2000/2003/XP operating system. Ascentia™ 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. Ascentia™ 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 ✓

David B. Lepore
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050228

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