Heartlab
CARDIAC SOLUTIONS

JUN 29 2005

Abbreviated 510(K) Summary

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

DATE: March 31, 2005

SUBMITTER:

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

OFFICIAL CONTACT PERSON:

Richard Petrocelli, President
Tel No: (401) 596-0592

510(k) SUBMITTAL CONTACT PERSON:

Lori Kahler, Director of Quality & Regulatory Affairs
Tel No: (401) 596-0592

IDENTIFICATION OF THE PRODUCT

TRADE NAME:	Ascentia HeartStation™ ECG Management System
COMMON NAME:	Ascentia HeartStation™
CLASSIFICATION NAME:	System, ECG Analysis Product Code LOS, 21 CFR 870.2340
	Computer, Diagnostic, Programmable Product Code DQK, 21 CFR 870.1425

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DEVICE DESCRIPTION / INTENDED USE:

The Ascentia HeartStation™ ECG Management System ("HeartStation™") is a comprehensive data management solution, which automates the processing, storage and display of electrocardiograms (ECGs) throughout a healthcare enterprise. HeartStation™ accepts standard 12-lead ECGs, which originate from any one of a variety of manufacturers' cardiographs and patient monitors, and normalizes them to a common format. ECGs are then measured, interpreted, compared to previous ECGs ("serial comparison"), optionally printed and stored with a preliminary diagnosis. A graphical user interface allows a physician to review these computer-generated reports, modify them or add comments as appropriate, electronically apply his or her signature and trigger the automatic distribution of final, confirmed diagnostic reports to other care providers.

HeartStation™ allows access to ECG records from web-enabled PCs throughout a network. Authorized clinical users may also access HeartStation™ from remote locations, including a home office. The type of access that is permitted depends on the role of the clinical user within the healthcare enterprise, and can include the ability to produce confirmed, signed diagnostic reports

Comprehensive workflow management software enables HeartStation™ to be tailored to the needs of the enterprise, resulting in the highest possible level of automation for routine tasks. The processing of an ECG can be adjusted depending on a patient's stage within the care process, from an emergency event to a routine follow-up test. Final ECG reports are distributed by printing, faxing, e-mailing and automatic exporting to other systems, including an electronic medical record.

A patient's confirmed ECGs become a part of his or her cardiology information and image record within the Heartlab Ascentia™ database. Authorized clinicians may review patients' integrated ECG, X-ray Angiography, Echocardiography and other cardiology tests through a web-enabled Ascentia Portal™.

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SUBSTANTIAL EQUIVALENCE INFORMATION:

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

Model	Manufacturer
Infinity MegaCare (k031970)	Dräger-Siemens
Eclipse ECG (k946281)	Burdick
Tracemaster ECG Management System (k032103)	Philips
Pyramis ECG Management System (k032038)	Quinton

Predicate device specifications comparison:

	Principal Device – Heartlab Ascentia HeartStation ™	**Predicate Device – Dräger-Siemens Infinity MegaCare**	**Predicate Device – Burdick Eclipse ECG**	**Predicate Device – Philips Tracemaster ECG Mgmt. System**	**Predicate Device – Quinton Pyramis ECG Mgmt. System**
Product description	ECG information management	ECG information management	ECG cart with software	ECG information management	ECG information management
User Interface	Off-the-shelf Personal Computer	Off-the-shelf Personal Computer	NA	Compaq Proliant ML 370 G3 server	Off-the-shelf Personal Computer
Operating System	Windows 2000/XP	Windows 2000	NA	Windows Server 2003	Windows 2000
Record export interface	TIFF, XML, PDF or HL-7	HL-7	NA	TIFF, XML, HL-7	HL-7
Display	17" (19" recommended) SVGA display, 1280 x 1024 min. resolution	Minimum resolution 1280 x 1024	NA	17" SVGA	Not specified
Web software	Microsoft Internet Explorer 6.0	Microsoft Internet Explorer 6.0	NA	Microsoft Internet Explorer 6.0	NA
Measurement model	Glasgow Interpretive ECG Program	Glasgow Interpretive ECG Program	Glasgow Interpretive ECG Program	Philips 12-lead algorithm	NA
Format translator	Datamed Format Translator (Engineering Solutions, Inc.)	Datamed Format Translator (Engineering Solutions, Inc.)	NA	Datamed Format Translator (Engineering Solutions, Inc.)	Datamed Format Translator (Engineering Solutions, Inc.)

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The similar predicate systems above provide information for qualified clinicians responsible for the diagnosis and treatment of patients (adult and pediatric) with heart disease.

The differences in the hardware platforms and off the shelf software used to operate the proposed device are considered to be improvements in the "state of the art" as compared to the predicate devices, and offer no affect to the safety or efficacy of the product.

STANDARDS:

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

1. 21 CFR 1020.10 Video Monitor Performance Requirements
2. 21 CFR 1040.10 Fiberoptic Communications Performance
3. Society of Motion Picture and Television Engineers (SMPTE)
4. ACR/NEMA Data Compression Standard
5. Underwriters Laboratories (U.L.) Standard No. 544 for Medical and Dental Equipment
6. Underwriters Laboratories (U.L.) Standard No. 1950 Safety Standards

SUMMARY OF DESIGN CONTROL ACTIVITIES:

The software utilized was designed, developed, tested and validated according to written Design Control procedures. These procedures specify individuals within the organization responsible for developing and approving product specifications, coding, testing, validating and maintenance. Potential hazards have been studied and controlled by a Risk Management Plan.

The following quality assurance design control measures were applied to the development of the Ascentia HeartStation™ 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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

Heartlab Inc.
c/o Ms. Lori Kahler
Director of Quality & Regulatory Affairs
One Crosswind Road
Westerly, RI 02891

Re: K050858
Trade Name: Ascentia HeartStation™ ECG Management System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: June 13, 2005
Received: June 14, 2005

Dear Ms. Kahler:

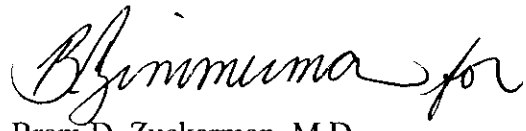
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 (240) 276-0295 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,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050858

Device Name: Heartlab Ascentia HeartStation™ ECG Management System

Indications For Use:

The Heartlab HeartStation™ ECG Management System is a comprehensive data management solution which automates the processing, storage and display of electrocardiograms (ECGs) throughout a healthcare enterprise. HeartStation™ accepts standard 12-lead ECGs, which originate from any one of a variety of manufacturers' cardiographs and patient monitors, and normalizes them to a common format. ECGs are then measured, interpreted, compared to previous ECGs ("serial comparison"), optionally printed and stored with a preliminary diagnosis. A graphical user interface allows a physician to review these computer-generated reports, modify them or add comments as appropriate, electronically apply his or her signature and trigger the automatic distribution of final, confirmed diagnostic reports to other care providers.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Richard Petrocelli, President Date: 6/22/05

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050858