SEP 2 1 2004

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:

27 July 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:	Ultrasound Capture System™ (UCS)
COMMON NAME:	Ultrasound Capture System / EcoCapture
CLASSIFICATION NAME:	Image Processing System, LLZ

DEVICE DESCRIPTION / INTENDED USE:

The Ultrasound Capture System™ (UCS) system captures analog video and audio from any ultrasound with a composite or S-video output and converts the captured video to DICOM image and audio files. UCS software runs on a standard "off-the-shelf" personal computer running the Windows XP operating system and a high-resolution video acquisition interface.

1. Allows demographic (Patient Name, ID etc.) input consistent with the DICOM standard for image storage.
2. Performs automatic image acquisition triggered by the cine-pedal.
3. Performs network transmission of images in DICOM format to a DICOM compatible storage system.

SUBSTANTIAL EQUIVALENCE INFORMATION:

Ultrasound Capture System (UCS) is considered comparable and substantially equivalent to the following predicate devices currently in commercial distribution:

Model	Manufacturer
CineCapture System (k990857)	Heartlab, Inc.
Echocardiography System (k992259)	Camtronics, Ltd.

Predicate device specifications comparison:

	Principal Device – Ultrasound Capture System	Predicate Device – Heartlab CineCapture System	Predicate Device – Camtronics Echocardiography System
Image Format	Lossy JPEG, DICOM 3.0	JPEG, DICOM 3.0	Lossy JPEG, DICOM 3.0
Compression	Variable, 10-12:1 recommended compression	Lossless, 512x512, 2:1, 8 bit	Up to 30:1
Video Source	S-video, or composite	High-line signal	RGB, YC, or composite
Display	1024x600 on small laptop, 1024x768 on standard laptop and desktop configurations	15" flat panel with speaker, up to 1024x768	17", 19", or 21" color monitors, up to 1024x1024 24 bit depth
Operating System	Windows XP	Windows 2000	Windows 2000
User Interface	Keyboard, mouse, and foot pedal	Keyboard, mouse, and foot pedal	User multifunction remote control, and mini-remote
Network	Fast Ethernet	Fast Ethernet	Fast Ethernet
DICOM	Yes	Yes	Yes

STANDARDS:

Ultrasound Capture System (UCS) 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 Fiberoptic 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)
8. 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 Ultrasound Capture System™ 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

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

7/28/04

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

7-28-04

Dated

CONCLUSIONS:

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

This concludes this 510(k) Summary.

Richard Petrocelli,
President
Heartlab, Inc

Attachments: Appendix A – Indications For Use
Appendix B – Ultrasound Capture System (UCS) Datasheet
Appendix C – Predicate Device Promotional Material – Heartlab – CineCapture System
Appendix D – Predicate Device Promotional Material – Camtronics – Echocardiography System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2004

Mr Richard Petrocelli
Official Correspondent
Heartlab, Inc.
One Crosswind Road
WESTERLY RI 02891

Re: K042042
Trade/Device Name: Ultrasound Capture System (UCS)
Regulation Number: 21 CFR 892.2030
Regulation Name: Medical image digitizer
Regulatory Class: II
Product Code: 90 LMA
Dated: July 27, 2004
Received: August 3, 2004

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 (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

K042042

~~K042042~~ Abbreviated 510(k) Encompass

Heartlab
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Attachment

Device Name: Ultrasound Capture System™ (UCS)

Indications For Use:

The Ultrasound Capture System™ (UCS) system captures analog video and audio from any ultrasound with a composite or S-video output and converts the captured video to DICOM image and audio files. UCS software runs on a standard "off-the-shelf" personal computer running the Windows XP operating system and a high-resolution video acquisition interface.

Prescription Use ✓

David A. Lyman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042042

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