K051325

APPENDIX B – 510(k) Summary of Safety and Effectiveness

JUN 15 2005

Heart Imaging Technologies, LLC

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR Part 807.92.

PART (a) – 510(k) Summary

(1) Identification of Submitter

Address:	Heart Imaging Technologies, LLC 327 West Main St. Durham, NC 27701
Registration Number:	3005107869
Contact Person:	Robert M. Judd, Ph.D. President Telephone: 919-384-5044 FAX: 866-457-3694
Date of Preparation:	May 9, 2005

(2) Identification of Device

Trade Name:	WebPAX
Common Name:	Picture archiving and communications system (PACS)
Regulation Number:	892.2050
Device Class:	II
Product Code:	LLZ

(3) Predicate Device

Manufacturer:	Siemens Medical Solutions, Inc.
Trade Name:	LEONARDO *syngo* Cardiology Workstation
Common Name:	Picture archiving and communications system (PACS)
Regulation Number:	892.2050
Device Class:	II
Product Code:	LLZ
510k Number:	K042203

(4) Description of Device

WebPAX is an integrated software and hardware package capable of communicating and storing medical images. WebPAX provides users with capabilities relating to the transfer, display, and storage of medical images as well as the ability to make geometric measurement of

features within the medical images. WebPAX is designed to be deployed over conventional TCP/IP networks and interacts with standard commercially-available computer platforms. WebPAX does not produce any original medical images; all images have been received from DICOM compliant scanners and workstations.

(5) Intended Use

WebPAX is intended for use in the communication and storage of medical images. WebPAX is also intended for use in viewing medical images and making geometric measurements on medical images over the world wide web.

(6) Technological Characteristics

Like the predicate device, WebPAX does not contact the patient nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention, interprets the images and information being displayed. The communication and storage components of the WebPAX system are essentially identical to those of the predicate device (eg. DICOM communication over TCP/IP networks, digital image storage on computer hard disk drives). Substantial equivalence of the geometric measurement component was determined based on non-clinical testing (see next section).

PART (b) – Performance Data

(1) Non-Clinical Tests

Medical images based on a plurality of imaging modalities were pushed to the predicate device using a standard DICOM network transfer. The identical medical images were pushed to the WebPAX system using the same standard DICOM network transfer. On both systems, geometric measurements were made on the plurality of medical images in a plurality of identical locations within each of the images and the results recorded for statistical comparison.

(2) Clinical Tests

Not applicable.

(3) Conclusions Drawn From Tests

No statistically significant differences were detected when comparing geometric measurements made using the WebPAX system with those of the predicate device. We conclude that the WebPAX system is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 2005

Robert M. Judd, Ph.D.
President
Heart Imaging Technologies, LLC
108 Barton Lane
CHAPEL HILL NC 27516

Re: K051325
Trade/Device Name: WebPAX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 15, 2005
Received: May 20, 2005

Dear Dr. Judd:

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

APPENDIX C – FDA Indications for Use Form

INDICATION FOR USE FORM

510(k) Number (if known): K051325

Device Name: WebPAX

Indications for Use:

WebPAX is intended for use in the communication and storage of medical images. WebPAX is also intended for use in viewing medical images and making geometric measurements on medical images over the world wide web.

(Please do not write below this line – continue on another page if needed)

Concurrence of the CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David G. Hyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051325