



Food and Drug Administration  
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Heart Imaging Technologies, LLC  
% Robert M. Judd, Ph.D.  
President  
5003 Southpark Drive, Suite 140  
DURHAM NC 27713

August 17, 2016

Re: K152949  
Trade/Device Name: WebPAX  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: July 27, 2016  
Received: August 1, 2016

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Robert Ochs, Ph.D." The signature is written in a cursive style and is positioned over a faint, large watermark of the letters "FDA".

For

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K152949

Device Name  
WebPAX

### Indications for Use (Describe)

WebPAX is intended for use in the communication and storage of medical images. WebPAX is also intended for use as a comprehensive solution to view, optimize, and post-process diagnostic medical images as an aid to physicians and other healthcare professionals in the evaluation of digital imaging examinations.

Due to special customer requirements based on the imaging modality and clinical focus, WebPAX can be configured with different combinations of clinical applications which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques such as multi-planar reconstruction (MPR).

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using cleared monitors intended for mammography display. MPR is not intended for mammography use.

Not intended for diagnostic use on mobile devices.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) Summary – K152949

### Identification of Submitter

Address: Heart Imaging Technologies, LLC  
5003 Southpark Drive, Suite 140  
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: July 29, 2016

### Identification of Device

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

### Predicate Devices

#### PREDICATE DEVICE 1:

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

#### PREDICATE DEVICE 2:

Manufacturer: Heart Imaging Technologies, LLC  
Trade Name: WebPAX  
Common Name: Picture archiving and communications system (PACS)  
Regulation Number: 892.2050  
Device Class: II  
Product Code: LLZ  
510k Number: K051325

### Description of Device

WebPAX consists of a server, typically located in a hospital data center, and one or more client systems used by technicians and physicians. On the server side, WebPAX is a software-only solution that is installed on customer-supplied hardware, such as dedicated computer server or virtual machine. The server-side software communicates with other DICOM-compliant systems and with end-users via

standard Intranet and/or Internet mechanisms. On the client side, technicians and physicians access the WebPAX server using standard Internet web browsers, such as Google Chrome and Internet explorer.

WebPAX provides users with the ability to manage, store, analyze and interpret digital medical images, including the following application specific modules:

- Echocardiography Workstation
- Cardiovascular MRI Workstation
- 3D Post Processing (Multi-Planar Reconstruction)

### **Indications for Use**

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Due to special customer requirements based on the imaging modality and clinical focus, WebPAX can be configured with different combinations of clinical applications which are intended to assist the physician in diagnosis or treatment planning. This includes commercially available post-processing techniques such as multi-planar reconstruction (MPR).

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Not intended for diagnostic use on mobile devices.

### **Performance Testing**

The following test reports have been provided in support of substantial equivalence:

#### **1. Software Verification Report**

The purpose of this report is to demonstrate that the WebPAX software meets all of the requirements described in the Software Requirement Specification. Testing was conducted with clients running on the two supported web browsers: Google Chrome and Microsoft Internet Explorer 11. All tests passed.

#### **2. Software Validation Report**

The purpose of this report was to validate the performance of the following WebPAX image analysis functionalities: Basic measurements, Echocardiography measurements, and Cardiovascular MR measurements. Testing was conducted with clients running on the two supported web browsers: Google Chrome and Microsoft Internet Explorer 11. [Note: Some functionalities are only available with the Google Chrome browser, and thus were only tested with that browser].

For all Software Validation tests for which the Predicate Device offered the same functionality, the “WebPAX Measurement Accuracy” was assessed by direct comparison to measurements made using the Predicate Device on the exact same DICOM dataset, image,

and location(s) within the image. In all cases WebPAX met the Acceptance Criteria that accuracy be greater than 98%.

### 3. Reader Study Report

The purpose of the Reader Study was to demonstrate that the 3D post processing capability of WebPAX 9.3 is equivalent to that of the predicate Siemens Leonardo Workstation (K042203). Three board-certified physicians who routinely read cardiovascular MRI studies were asked to evaluate six DICOM datasets that represent typical clinical scenarios. All scores for WebPAX were at least a 1 (Excellent) or a 2 (Very good). The performance of WebPAX was comparable to that of the predicate Siemens device.

### Substantial Equivalence Discussion

The following table compares WebPAX to the predicate device:

FEATURE	WebPAX	Predicate Device (Siemens Leonardo K042203)	Comments
<b>Basic PACS Functions</b>			
TCP/IP network connectivity	Yes	Yes	DICOM standard
DICOM storage class provider (SCP)	Yes	Yes	DICOM standard
DICOM storage class user (SCU)	Yes	Yes	DICOM standard
Digital image storage	Yes	Yes	DICOM standard
Image visualization	Yes	Yes	DICOM standard
<b>Generic Tools</b>			
Distance Measurements	Yes	Yes	DICOM standard
ROI Area Measurements	Yes	Yes	DICOM standard
ROI Grayscale Measurements	Yes	Yes	DICOM standard
Angle Measurements	Yes	Yes	Basic Geometry
<b>Specialty Tools: Echocardiography</b>			
Doppler Velocity	Yes	No	DICOM standard
Deceleration Time	Yes	No	DICOM standard
Velocity-Time Integral	Yes	No	DICOM standard
Stress Echo Display	Yes	No	DICOM standard
<b>Specialty Tools: Cardiovascular MRI</b>			
Volumes/Mass	Yes	Yes	ROI Area times Slice Thickness
Hyperintensity	Yes	Yes	ROI Area times Slice Thickness
Velocity Encoding	Yes	Yes	ROI Grayscale times Scale Factor
Time-Intensity Curves	Yes	Yes	ROI Grayscale versus time
T2 and T2* Decay	Yes	No	ROI Grayscale versus time
T1 Recovery	Yes	No	ROI Grayscale versus time
<b>3D Post Processing</b>			
Multi-Planar Reconstruction	Yes	Yes	For WebPAX, based on WebGL

Both the WebPAX and Siemens Leonardo devices provide generic PACS functionalities with common measurement tools and basic image processing.

Both devices also provide specialty tools for Cardiovascular MRI that allow assessment of cardiac volumes, masses, blood flow velocities, and time-intensity curves. The performance of these functions for both devices were directly compared. WebPAX also provides users with the ability to fit a mono-exponential curve to MRI T2(\*) and/or T1 grayscale data based on well-established techniques.

WebPAX additionally provides specialty tools for Echocardiography. Although the Siemens Leonardo does not provide Echocardiography functions, all of these are an integral part of the DICOM standard itself and testing demonstrated that performance met established acceptance criteria.

Both devices provide multi-planar reconstruction (MPR) techniques that allow the user to re-slice 3D data into directions other than the original imaging planes. The underlying technology used by WebPAX to achieve this, namely WebGL, is different than that used by the Siemens Leonardo, but a reader study demonstrated equivalent performance.

### **Summary of Substantial Equivalence**

No significant differences were detected when comparing measurements and post-processing results made using the candidate WebPAX system with those of the predicate devices. We conclude that the WebPAX system is substantially equivalent.