K110332

MAR 2 4 2011

510(k) Summary of Safety and Effectiveness

Date Prepared

November 22, 2010

Submitter

ClearCanvas Inc.
439 University Ave., Suite 1920
Toronto, ON M5G 1Y8
Canada

Contact Person

Clinton Chau
Email: clinton@clearcanvas.ca
Phone: (647) 547-2987
Fax: (866) 584-5688

Device Name and Classification

Trade Name	ClearCanvas RIS/PACS
Common Name	Picture Archiving and Communications System (PACS)
Device Classification Name	System, Image Processing, Radiological
Device Class	Class II
Regulation Number	892.2050
Product Code	LLZ
Classification Panel	Radiology

Predicate Devices

Trade Name	BRIT PACS SYSTEMS	IntelePACS(tm)
Model Number	--	--
Common Name	Picture Archiving and Communication System (PACS)	Picture Archiving and Communication System (PACS)
510(k) Submitter/ Holder	BRIT Systems Inc. 1909 Hi-Line Dr. Dallas, TX 75207	Intelerad Medical Systems Inc. Anibal Jodorcovsky 460 Ste-Catherine West, Suite 210 Montreal, QC Canada H3B 1A7
510(k) Number	K081168	K070080
Regulation Number	892.2050	892.2050
Panel	Radiology	Radiology
Product Code	LLZ	LLZ

Device Description and Intended Use

ClearCanvas RIS/PACS is a Picture Archiving and Communication (PACS) software system for the management and review of medical image data, and other digital images. Such data can be received from all DICOM-compliant imaging modalities or imported directly into the system. This data can then be stored, archived, distributed, processed, enhanced, analyzed and displayed for review. Enhancement, processing and analysis of the image data includes but is not limited to compression/decompression, magnification, value-of-interest manipulation, orientation changes, image fusion and multiplanar reformat. Additional health data, such as patient demographics, from other information systems can be received from HL7-compliant sources.

The ClearCanvas RIS/PACS is a system of interrelated software components:

- **ClearCanvas Workstation** – a desktop client that is primarily used to retrieve, display, enhance and analyze medical images. Access to patient demographic data is also possible through the Workstation when working with the RIS server.
- **ClearCanvas Webstation** – a browser-based web application that allows the user to retrieve images from the ImageServer for review. Primarily intended for referring physicians and as an image viewer for EMR systems, the images are JPEG-compressed.
- **ClearCanvas ImageServer** – a server application that receives images from imaging modalities, stores and archives them, and distributes them to client applications.
- **ClearCanvas RIS** – a server application that acts as an online transaction processor for the management of patient and workflow information.
- **ClearCanvas IntegrationServer** – a server application composed of optional modules that implement integration and interoperability, such as an inbound and outbound HL7 processor.
- **ClearCanvas EnterpriseServer** – a server application that provides enterprise-wide facilities such as user authentication, authorization and auditing.

Working in concert or stand-alone, each component plays a valuable role in the management information in the radiology reading room, the clinic, the referring physician's office, or any other patient care setting where access to medical imaging information is important.

ClearCanvas RIS/PACS software is primarily written in C#, employing the most current best practices in object-oriented and component-oriented software architecture resulting in a highly scalable and extensible design. The system is also designed to work on generic PC hardware that meets the minimum system requirements.

Indications for Use

The ClearCanvas RIS/PACS is an image management system whose intended use is to provide scaleable DICOM compatible PACS solutions for hospitals and related institutions and sites, which will archive, distribute, retrieve and display images and data from all hospital modalities (such as CR, CT, DR, MR, and other devices) and information systems. This also includes the display of structured reports and mammography images that have been created according to DICOM "For Presentation", and will include standard features and other tools for analyzing mammography images.

Lossy compressed mammography images and digitized film screen images must not be used for primary image interpretations. Mammography images may only be interpreted using an FDA approved monitor that offers at least 5 mega-pixel resolution and meets other technical specifications approved by the FDA.

Technological Characteristics

The ClearCanvas RIS/PACS has no patient contact and does not control any life sustaining devices. It is a software PACS device used in the management of medical imaging information. This device is used by trained and qualified professionals affording ample opportunity for competent human intervention in interpreting the images and information presented. These technological characteristics are identical to those in the predicate devices. Furthermore, the following comparison table summarizes the specific characteristics of the ClearCanvas RIS/PACS and its predicate devices that demonstrate substantial equivalence:

		Subject Device	Predicate Device	Predicate Device
	Trade Name	ClearCanvas RIS/PACS	BRIT PACS SYSTEM	IntelePACS
	Intended Use			
1	To be used as a Picture Archive and Communication System (PACS)	Y	Y	Y
2	To be used for storing and distributing images	Y	Y	Y
3	To be used for displaying, analyzing, manipulating and enhancing of images	Y	Y	Y
	Indications For Use Statement			
4	Statement uses the term, "picture archive and communication system" or "PACS"	Y	Y	Y
5	Statement references the display of medical images	Y	Y	Y
6	Statement references receiving images from image sources	Y	Y	Y

		Subject Device	Predicate Device	Predicate Device
7	Statement references multi-planar reformat	N	N	Y
8	Statement references mammographic images	Y	Y	Y
	Standards Met			
9	Conforms to the essential requirements of the DICOM standard for data exchange (PS 3.3-PS 3.12)	Y	Y	Y
10	Conforms to the JPEG standard for image compression of digital medical images	Y	Y	Y
	Design			
11	Software device that operates on off-the-shelf hardware	Y	Y	Y
12	Device is a system composed of multiple components that work stand-alone or in concert	Y	Y	Y
13	Device components are organized in a client-server architecture	Y	Y	Y
14	Medical image viewer, the client application, is a key component of the device system	Y	Y	Y
15	Image storage and archive server, the server application, is a key component of the device system	Y	Y	Y

		Subject Device	Predicate Device	Predicate Device
	Functions and Capabilities			
16	Query, import, send, receive DICOM images	Y	Y	Y
17	Image analysis tools W/L, zoom, pan, stack, rotation, flip	Y	Y	Y
18	Measurement and annotation	Y	Y	Y
19	Multi-monitor awareness	Y	Y	Y
20	Image layout	Y	Y	Y
21	Image Thumbnails	Y	Y	Y
22	Reference lines and spatial locator for tomographic images	Y	Y	Y
23	User annotations of images	Y	Y	Y
24	Synchronized stacking	Y	Y	Y
25	Probe tool	Y	N	Y
26	Shutters	Y	N	Y
27	Key Image marking	Y	Y	Y
28	Multiplanar Reformat (MPR)	Y	Y	Y
29	Lossy and lossless image compression	Y	Y	Y
30	Automatic routing of images	Y	Y	Y
31	Image archiving	Y	Y	Y

		Subject Device	Predicate Device	Predicate Device
32	Patient information and workflow management components	Y	Partial	Y
33	Image streaming from server	Y	Y	N
34	Operating System/Platform	Windows	Linux and Windows	Linux and Windows
35	DICOM image printing	Y	Y	Y
36	Export DICOM images to optical media	Y	Y	Y
37	PET/CT fusion	Y	Y	N
	Other Areas of Comparison			
38	Target population	No restrictions	No restrictions	No restrictions
39	Anatomical sites	No restrictions	No restrictions	No restrictions
40	Environment for use	No restrictions; to be used by trained professionals only	No restrictions; to be used by trained professionals only	No restrictions; to be used by trained professionals only
41	Energy used and/or delivered	Electric power supply to computer hardware only	Electric power supply to computer hardware only	Electric power supply to computer hardware only
42	Human factors	Standard windows-based or web-based graphical user interfaces, with standard input devices	Standard windows-based or web-based graphical user interfaces, with standard input devices	Standard windows-based or web-based graphical user interfaces, with standard input devices

		Subject Device	Predicate Device	Predicate Device
43	Performance	Real-time performance requirements not applicable	Real-time performance requirements not applicable	Real-time performance requirements not applicable
44	Materials	Not applicable	Not applicable	Not applicable
45	Biocompatibility	Not applicable	Not applicable	Not applicable
46	Compatibility with environment and other devices	Interoperation with other devices based on consensus standards on data exchange (DICOM)	Interoperation with other devices based on consensus standards on data exchange (DICOM)	Interoperation with other devices based on consensus standards on data exchange (DICOM)
47	Sterility	Not applicable	Not applicable	Not applicable
48	Electrical safety	Not applicable	Not applicable	Not applicable
49	Mechanical safety	Not applicable	Not applicable	Not applicable
50	Chemical safety	Not applicable	Not applicable	Not applicable
51	Thermal safety	Not applicable	Not applicable	Not applicable
52	Radiation safety	Not applicable	Not applicable	Not applicable
	Product Labelling			
53	Instructions for searching and retrieval of images	Y	Y	Y
54	Instructions for displaying of images	Y	Y	Y

		Subject Device	Predicate Device	Predicate Device
55	Instructions for manipulating orientation of images	Y	Y	Y
56	Instructions for enhancing images	Y	Y	Y
57	Instructions for annotating images	Y	Y	Y

Testing

The ClearCanvas RIS/PACS complies with the voluntary DICOM and JPEG standards for device performance and is designed and manufactured according to the process and management system standards set in ISO 13485:2003 and ISO 62304, as discussed in the 510(k) submission.

Performance testing was conducted to verify the design output met the design input requirements and to validate the device conforms to the defined user needs and intended uses. Nonclinical software testing, as well as human factors testing, was conducted under simulated use conditions. Predefined acceptance criteria were met and demonstrated that the device is as safe and as effective as the predicate devices.

Substantial Equivalence Conclusions

ClearCanvas concludes that the intended use for the ClearCanvas RIS/PACS is the same as that of the predicate devices, and that the technological characteristics demonstrate that they are equivalent to the predicate devices. A comparison of the technological characteristics of the predicate and legally marketed devices available has been performed.

Conclusion

The 510(k) Pre-Market Notification for ClearCanvas RIS/PACS contains adequate information and data to determine that ClearCanvas RIS/PACS is as safe and effective as the legally marketed predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

ClearCanvas, Inc.
% Ms. Paula Wilkerson
Sr. Staff Engineer-Medical Devices
Intertek Testing Services
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

MAR 24 2011

Re: K110332
Trade/Device Name: ClearCanvas RIS/PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 15, 2011
Received: March 16, 2011

Dear Ms. Wilkerson:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110332

Device Name: ClearCanvas RIS/PACS

Indications for Use:

The ClearCanvas RIS/PACS is an image management system whose intended use is to provide scaleable DICOM compatible PACS solutions for hospitals and related institutions and sites, which will archive, distribute, retrieve and display images and data from all hospital modalities (such as CR, CT, DR, MR, and other devices) and information systems. This also includes the display of structured reports and mammography images that have been created according to DICOM "For Presentation", and will include standard features and other tools for analyzing mammography images.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

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