October 11, 2018

OnePacs, LLC
Justin Falk
Director of IT
530 Lytton Ave
PALO ALTO, CA 94301

Re: K181460
Trade/Device Name: OnePacs System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 29, 2018
Received: September 11, 2018

Dear Justin Falk:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181460

Device Name
OnePacs System

Indications for Use *(Describe)*

The OnePacs System is an image management system intended 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 mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. For primary diagnosis, post process DICOM "for presentation" images must be used. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images.

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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SECTION 5

510(k) Summary

K181460

1. Sponsor

OnePacs, LLC
530 Lytton Ave
Palo Alto, CA 94301
Phone: 877-881-7227 x117
Fax: 201-399-6580
Contact: Justin Falk
Email: jfalk@onepacs.com

Summary Preparation Date: May 29, 2018

2. Device

Trade Name	OnePacs System
Common Name	Picture archiving and communications system (PACS)
Classification	Class II
Product Code	LLZ
Regulation Number	21 CFR 892.2050
Review Panel	Radiology

3. Predicate Device

- ClearCanvas RIS/ PACS (K110332)
- OsiriX MD (K101342)

4. Device Description

The OnePacs System is an image management system intended 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.

The OnePacs system is a software only product and does not include any hardware accessories or peripheral devices. It is designed to work on generic PC hardware that meets minimum system requirements.

The OnePacs System is comprised of following main interrelated software elements/ components:

- OnePacs Cloud (OPS)
- OnePacs Workstation (OPW)
- OnePacs Workstation for macOS (OPX)
- OnePacs Webviewer (OPWEBV)
- OnePacs Study Retriever (OPSR)
- OnePacs Gateway (OPG)

5. Indications for Use

The OnePacs System is an image management system intended 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 mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. For primary diagnosis, post process DICOM "for presentation" images must be used. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images

6. Technological Characteristics and Substantial Equivalence

The proposed OnePacs System is substantially equivalent to the referenced predicate devices in regard to the intended use, fundamental scientific technology, and technological characteristics, as outlined in the following table:

Characteristic	**Subject Device**	**Predicate Device**	**Predicate Device**
Trade Name	**OnePacs System**	**ClearCanvas RIS/PACS (K110332)**	**OsiriX MD (K101342)**
Submitter	OnePacs LLC	ClearCanvas Inc.	Pixmeo, Sarl
Classification	Device Class: 2 Product Code: LLZ 21 CFR 892.2050	Device Class: 2 Product Code: LLZ 21 CFR 892.2050	Device Class: 2 Product Code: LLZ 21 CFR 892.2050
Indications for Use	The OnePacs System is an image management system intended to provide scaleable DICOM compatible PACS solutions for hospitals and related institutions and	The ClearCanvas RIS/PACS is an image management system whose intended use is to provide scaleable DICOM compatible PACS solutions for hospitals and	OsiriX MD is a software device intended for viewing of images acquired from CT, MR, CR, DR, US and other DICOM compliant medical

Characteristic	Subject Device	Predicate Device	Predicate Device
Trade Name	**OnePacs System**	**ClearCanvas RIS/PACS (K110332)**	**OsiriX MD (K101342)**
	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 mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. For primary diagnosis, post process DICOM "for presentation" images must be used. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images.	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.	imaging systems when installed on suitable commercial standard hardware. Images and data can be captured, stored, communicated, processed, and displayed within the system and or across computer networks at distributed locations. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary diagnosis or image interpretation. For primary diagnosis, post process DICOM "for presentation" images must be used. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. It is the User's responsibility to ensure monitor quality, ambient light conditions, and image compression ratios are consistent with the clinical application.

Characteristic	Subject Device	Predicate Device	Predicate Device
Trade Name	**OnePacs System**	**ClearCanvas RIS/PACS (K110332)**	**OsiriX MD (K101342)**
Prescription / Over-The-Counter (OTC) Use	Prescription Use	Prescription Use	Prescription Use
Device Description and Key Components	The OnePacs System software is primarily written in Java/ Javascript. The system is designed to work on generic PC hardware that meets minimum system requirements. The OnePacs System is comprised of following interrelated software components: <u>OnePacs Cloud</u> OnePacs Application Server is inherently enterprise wide, deployed in multi-tenant cloud architecture. The OnePacs Cloud allows medical studies to be securely transmitted so that a physician may view and interpret the study and complete the medical report. <u>OnePacs Workstation (OPW) & OnePacs Workstation for macOS (OPX)</u> Communicates with OnePacs Server for image retrieval and metadata. The OPW and OPX provide navigation and visualization of multi-modality and multidimensional images. They act as DICOM viewer capable of connecting to a DICOM network <u>OnePacs Web Viewer (OPWEBV)</u> enables the display and	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. The ClearCanvas RIS/PACS is a system of interrelated software components: <u>ClearCanvas Workstation</u> 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. <u>ClearCanvas Webstation</u> 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. <u>ClearCanvas ImageServer</u>	The OsiriX MD software is an interactive image display and navigation program that was designed to display medical imaging modalities. It supports all types of images generated by variety of imaging equipment and scanners available today. It supports the DICOM standard for image communication as well as a variety of other image formats used in academic and research community. OsiriX MD is tailored for large sets of multidimensional and multi-modality images such as combined PET-CT studies that require three-dimensional image fusion and volume rendering. The software is developed on a Macintosh platform taking advantage of the underlying UNIX kernel of the Mac OS X operating optimized 3D graphic capabilities of Open GL graphic standard that is widely used for computer games and animations and is highly optimized on the Macintosh platform for taking advantage of any hardware graphic accelerator boards that would be available. The software was developed in Objective-C in Apple Cocoa development environment. In the design of the software a

Characteristic	Subject Device	Predicate Device	Predicate Device
Trade Name	**OnePacs System**	**ClearCanvas RIS/PACS (K110332)**	**OsiriX MD (K101342)**
	review of medical images OnePacs Study Retriever (OPSR) facilitates the secure transmission of medical images from the OnePacs Cloud servers to the local desktop of a radiologist. OnePacs Gateway (OPG) a gateway or bridge to the OnePacs Cloud. The OPG software enables access to the cloud by offering the following functionality. It provides DICOM image routing, security, and compression, HL7 mapping connectivity and mapping	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.	special attention was given to adapt the user interface to navigating through large sets of image data. The graphical user interface also uses the Macintosh interface. Users can change and customize the software by adding and removing tools and items from the program toolbar and menu bars. This allows for adapting the software for number of functions and avoiding the users to be overwhelmed by an excessive number of unnecessary tools and functions that are not always needed.
Operating system/ platform	Windows, Mac OS X (Apple), Linux	Windows	Mac OS X (Apple)
Device type/ form	Software device that operates on off-the-shelf hardware	Software device that operates on off-the-shelf hardware	Software device that operates on off-the-shelf hardware
Mode of delivery/ installation	OnePacs System is to be downloaded from OnePacs Cloud. The OPX component is provided as a macOS package download. The package is installed through the macOS Installer tool.	Installation from optical media and/ or download from the server	OsiriX MD is provided as a DMG (Apple Disk Image) download. When mounted, the DMG offers an installer application to be executed by the user.

Characteristic	Subject Device	Predicate Device	Predicate Device
Trade Name	**OnePacs System**	**ClearCanvas RIS/PACS (K110332)**	**OsiriX MD (K101342)**
Functions and Capabilities			
Query, Import, Send, Receive DICOM images	Yes	Yes	Yes
Image Printing	Yes	Yes	Yes
Export of DICOM images to optical media	Yes	Yes	Yes
Reporting – save, email, DICOM send, or print to standard printers	Yes	Yes	Yes
Image analysis tools W/L, zoom, pan, stack, move, rotate, flip, and delete	Yes	Yes	Yes
Measurement and annotation	Yes	Yes	Yes
Multi-monitor awareness	Yes	Yes	Yes
Image layout	Yes	Yes	Yes
Image thumbnails	Yes	Yes	Yes
Reference lines and spatial locator for tomographic images	Yes	Yes	Yes
User annotations of images	Yes	Yes	Yes
Synchronized stacking	Yes	Yes	Yes
Probe tool	Yes	Yes	Yes
Shutters	Yes	Yes	Yes
Key image marking	Yes	Yes	Yes

Characteristic	Subject Device	Predicate Device	Predicate Device
Trade Name	**OnePacs System**	**ClearCanvas RIS/PACS (K110332)**	**OsiriX MD (K101342)**
Multiplanar Reformat (MPR)	Yes	Yes	Yes
Lossy and lossless compression	Yes	Yes	Yes
Automatic routing of images	Yes	Yes	Yes
Image archiving	Yes	Yes	Yes
Patient information and workflow management components-	Yes	Yes	Yes
Image streaming from server	Yes	Yes	Yes
PET/CT fusion	No	Yes	Yes
Enterprise distribution of images and data via Internet or Intranet	Yes	Yes	Yes
Web-delivered viewing software	Yes	Yes	Yes
Conformity to Standards			
• DICOM standard for data exchange	NEMA PS 3.1 - 3.20 (2016) Digital Imaging And Communications In Medicine (Dicom) Set	Conformity to the essential requirements of the DICOM standard for data exchange (PS 3.3 – PS 3.12)	Conformity to the essential requirements of the DICOM standard for data exchange (PS 3.3 – PS 3.12)
• JPEG standard for image compressio n	IEC/ ISO 10918-1, Edition 1 (1994-02-15), Information Technology - Digital Compression And Coding Of Continuous-Tone Still Images: Requirements And Guidelines [Including: Technical Corrigendum 1 (2005)	IEC/ ISO 10918-1, Edition 1 (1994-02-15), Information Technology - Digital Compression And Coding Of Continuous-Tone Still Images: Requirements And Guidelines [Including: Technical Corrigendum 1 (2005)	IEC/ ISO 10918-1, Edition 1 (1994-02-15), Information Technology - Digital Compression And Coding Of Continuous-Tone Still Images: Requirements And Guidelines [Including: Technical Corrigendum 1 (2005)

The indications for use of the OnePacs System are similar to the indications for use of the referenced predicate devices. No new indications are claimed for the OnePacs System. Fundamentally, the OnePacs System is the same as the referenced predicate devices in that it is an image management system. As detailed above in the comparison table, most of their specifications and features are also same and comparable.

The ClearCanvas Workstation is chosen as one of the predicates for this submission for comparing the 'OnePacs Workstation for Windows' i.e. the OPW element of OnePacs System. The OPW was designed to use the ClearCanvas Workstation (CCW) as an application framework. The core implementation of the CCW was relatively complete as a viewer, but was also designed to be highly extensible. The majority (but not all) of OPW-specific functionality has been implemented as plug-ins, leaving the base CCW code mostly as-is, except where such functionality was not possible via the plug-in interface.

The OsiriX MD is chosen as one of the predicates for this submission for comparing the OnePacs Workstation for macOS i.e. the OPX element of OnePacs System. The final free/open source version of OsiriX released as version 5.8 was used as the starting point to develop OnePacs Workstation for macOS (OPX). The OsiriX was rebranded to Horos without introduction of any new features. OnePacs further rebranded Horos to OPX with the changes described further in this section.

The differences between the OnePacs System and the predicate devices ClearCanvas and OsiriX MD mainly relate to the changes in GUI, plugins, defaults, reporting, rebranding, Region Preferences and Certifications. These differences have been addressed through comprehensive software validation performed by OnePacs; and thereby do not raise any new concerns of safety or effectiveness.

7. Non-clinical Bench (Performance) testing

The performance testing includes the comprehensive software validation as provided in the submission. In addition, the OnePacs System complies with the following performance standards:

- NEMA PS 3.1 - 3.20 (2016) Digital Imaging And Communications In Medicine (Dicom) Set
- IEC/ ISO 10918-1, Edition 1 (1994-02-15), Information Technology – Digital Compression and Coding Of Continuous-Tone Still Images: Requirements And Guidelines [Including: Technical Corrigendum 1 (2005)

8. Clinical Testing

The submission does not contain any data from clinical testing.

9. Conclusion:

Based on the intended use, technological characteristics and performance data provided in the submission; the proposed 'OnePacs System' is substantially equivalent to the referenced predicate devices.