DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Healthmyne, Inc.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO, MN 55313

August 20, 2015

Re: K152186
Trade/Device Name: Healthmyne PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 4, 2015
Received: August 5, 2015

Dear Mr. Job:

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152186

Device Name
HealthMyne PACS

Indications for Use *(Describe)*
The HealthMyne PACS software is a Picture Archiving and Communications System (PACS) intended to be used as a Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. The HealthMyne PACS software displays, processes, stores, and transfers medical data from original equipment manufacturers (OEMs) that support the DICOM (including DICOM-RT) standard, with the exception of mammography. It provides the capability to store images and patient information from OEM equipment, and perform filtering, digital manipulation and quantitative measurements.

The client software is designed to run on standard personal and business computers. The product is intended to be used by trained medical professionals, including but not limited to radiologists, oncologists, and physicians. It is intended to provide image and related information that is interpreted by a trained professional to render findings and/or diagnosis, but it does not directly generate any diagnosis or potential findings.

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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Summary of Safety and Effectiveness/510k Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

Company	HealthMyne, Inc. 918 Deming Way Madison, WI 53717
Contact	Sigrid Schoepel Director of Regulatory Affairs Telephone: 608-833-2610 Email: sigrid.schoepel@healthmyne.com
Preparation Date	June 15, 2015, Revised July 17, 2015
Trade Name	HealthMyne PACS
Classification	Class II per 21 CFR 892.2050 Picture Archiving and Communications System
Product Code	LLZ

Marketed Devices

HealthMyne PACS is a new software-only medical device that can manage OEM medical diagnostic images that are compatible with the DICOM standard. It performs functions similar to those currently available in the Horizon Medical Imaging software cleared for marketing via 510(k) K043146 by McKesson Medical Imaging Company.

Device Description

HealthMyne PACS accesses the information in real-time so that current patients and images are available to a clinician. The clinician can filter and search the patient and image metadata to find the desired patient(s) and/or image(s). The clinician can view the images in various hanging protocol layouts. The layouts contain viewports of the slices within the image set, each annotated with patient information. Within the viewports the clinician can manipulate the image using standard tools: scroll, pan, zoom, window and level, and view the location of the slice in other viewports.

Intended Use

The HealthMyne PACS software is a Picture Archiving and Communications System (PACS) intended to be used as a Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. The HealthMyne PACS software displays, processes, stores, and transfers medical data from original equipment manufacturers (OEMs) that support the DICOM (including DICOM-RT) standard, with the exception of mammography. It provides the capability to store images and patient information from OEM equipment, and perform filtering, digital manipulation and quantitative measurements.

The client software is designed to run on standard personal and business computers. The product is intended to be used by trained medical professionals, including but not limited to radiologists, oncologists, and physicians. It is intended to provide image and related information that is interpreted

by a trained professional to render findings and/or diagnosis, but it does not directly generate any diagnosis or potential findings.

Comparison with Predicate

HealthMyne PACS performs many diagnostic image management picture archiving and communications functions available in the predicate device as shown in the following comparison chart. Its intended uses are similar to those of the predicate.

Element	Predicate – McKesson (K043146)	Submission - HealthMyne
Device Name	Horizon Medical Imaging	HealthMyne PACS (HM PACS)
510(k) owner	McKesson Medical Imaging Company	HealthMyne, Inc.
Supports mammography	Yes.	No.
Operating System	The product uses a client-server architecture utilizing Windows and web-based platforms.	The product uses a client-server architecture utilizing Windows and Linux platforms.
Image storage/ compression	Supports JPEG200 and compression.	Supports JPEG2000 and compression.
DICOM compliant	Yes.	Yes.
Worklists	Yes.	Yes
Filter and search capabilities	Yes.	Yes.
Ability to search studies	Yes. Specific searchable fields.	Yes. Dynamic (freeform) search and matching. Also customizable, indexed search parameters.
View study-related documents	Yes. Can view reports/documents.	Yes. Presentation states and RT Struct (regions of interest)
Priority "stat" studies	Yes. Customizable priority settings and email notification.	Yes. Studies with a DICOM priority tag ("Stat" studies) are given priority order (top of the list) in the exam view.
Manage pushed studies	Yes. Configurable whether studies from other systems can be sent to this product.	Yes. This product supports only pushed studies. No studies originate within this product.
View current and prior studies at the same time	Yes. Called anchor (labeled with an A) study and reference (labeled with an R) study.	Yes. Called current study and prior study. Prior studies have a large "PRIOR" label in each viewport.
Open studies with no digital images	Yes	No
Re-organize series in a study (for viewing)	Yes. Has a thumbnail view and a viewport selector to choose which viewport to populate. Can save the order.	Yes. Has a thumbnail view with the ability to drag and drop the thumbnail into a viewport. Cannot save the order.

Element	Predicate – McKesson (K043146)	Submission - HealthMyne
Display all study images in one viewport	Yes. Can choose to make a viewport show all images within a study.	No.
Create separate displays	Yes. Can select to show just a single series in a set of windows.	Yes. Can display a viewport as a single viewport, can select a viewport layout and add series to it.
Cycle through series	Yes. Can show the "next" and "previous" sets of series.	Yes. Can show the "next" and "previous" sets of series.
Image display modes	Yes. Static and cine.	Yes. Static and manual cine.
Select images	Yes. There is an active image indicator and the active image can be chosen. Can flag/bookmark an image.	Yes. There is an active image indicator. The active image can be chosen or is automatically set based on tool use.
Delete images	Yes. With the right permission and from the client/web software.	Yes. Only with PACS admin privileges and from the admin console.
Sort images	Yes. Can choose a sort order in the viewport layout.	Yes. Sorting and grouping are by system-defined rules.
Copy images	Yes. Can copy an image to the clipboard.	No.
Scrolling through slices	Yes. Linked series are scrolled together. Can perform "power scrolling" to move through slices quickly.	Yes. Linked series are scrolled together. Can "swipe" on a scroll bar to move through slices quickly. Can lock/unlock scrolling through every image.
Zoom in/out	Yes. Default settings and can zoom interactively.	Yes. Default settings and can zoom interactively.
Magnify an area	Yes. Can select an area of an image and zoom on just that area.	No, though a similar tool allows a user to magnify a region interactively.
Pan an image	Yes	Yes
Standard viewport layouts	Yes. Viewport layouts that are independent of any modality or common features of series.	Yes. Viewport layouts that are independent of any modality or common features of series.
Custom layouts	Yes.	No. Viewport layouts and hanging protocols are factory-default.
Labels	Yes. There are labels in the viewport for patient, study, and image information. Can toggle the display on/off.	Yes. There are labels in the viewport for patient, study, and image information.
Orientation labels	Yes.	Yes.
Cross-reference indicator	Yes. There are cross-reference lines to indicate intersection.	Yes. There is a cutline in linked viewports to indicate intersection.
View DICOM data	Yes. You can view the DICOM information about the patient and study, and the pixel information.	Yes. You can view the DICOM information about the patient, study, and current image.
Create MPR images	Yes. Images can be saved only in the advanced version of the product.	No. MPRs from the external source are supported/displayed.

Element	Predicate – McKesson (K043146)	Submission - HealthMyne
Window/level determination	Determined by the product's lookup tables (5 variations), the scanner's lookup table, or a histogram.	Determined by a lookup table function (linear) and the W/L values of the image. If the image has a custom lookup table or a fixed W/L, those settings are used instead of allowing changing of W/L. If no W/L, then a histrogram is used.
Window/level across series	Yes. W/L settings can be applied to selected images, series, or all visible.	Yes. W/L settings are applied to the active image and any linked images.
Window/level presets	Yes. Factory-default and customer-defined.	Yes. Factory default.
Adjust window/level	Yes. Can interactively adjust the window and level.	Yes. Can interactively adjust the window and level.
Post-processing of images	Yes. Can sharpen/smooth images except for mammography.	No. No post-processing.
Annotation	Yes. Can add temporary (per session) or permanent annotations.	Yes. Display only.
Measuring tools	Yes. Linear, scale, angles, and pixel intensity of a point.	Yes. Pixel intensity and location.
Store presentation states	Yes. Can group and save visualization settings.	No. Only display of presentation states.
Detect image/patient issues	Yes. Has a "QA" feature to indicate patient mismatch/image issues.	Yes. Can view patients and studies with errors.
Print reports	Yes.	No.
Custom hanging protocols	Yes.	No. Comes with factory-default hanging protocols.
Custom filters	Yes. Can set filters to affect the studies listed.	Yes. Can set filters to affect the studies listed.
Set reading state	Yes. Ability to set study status.	Yes. Can mark a study as read.
Custom search groups	No.	Yes. Can set "codes" to index elements for searching (for example, referring physician or sets of exam types) for faster auto-complete during search.
Display radiation therapy information	Yes. Supports DICOM RT information.	Yes. Supports DICOM RT structures.

Summary of Studies

The HealthMyne PACS software has undergone verification and validation to confirm its functional performance. Non clinical testing confirmed conformance to the following FDA recognized industry standards applicable to PACS devices: DICOM standard for medical diagnostic images, SMPTE display, and the JPEG2000 image standard.

Conclusion

It is the opinion of HealthMyne, Inc. that HealthMyne PACS software is substantially equivalent to similar image management options available in the predicate device. HealthMyne PACS does not include any new indications for use with regards to the management of medical diagnostic images, nor does use of this software result in any new potential hazards.