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

January 15, 2016

HealthMyne, Inc.
% Mr. Mark Job
Responsible Third Party Official
1394 25th Street, NW
BUFFALO MN 55313

Re: K153289
Trade/Device Name: HealthMyne
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 31, 2015
Received: January 4, 2016

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,

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

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)*
K153289

Device Name
HealthMyne

Indications for Use *(Describe)*
The HealthMyne 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 software displays, processes, stores, and transfers medical data from original equipment manufacturers (OEMs) that support the HL7 and DICOM (including DICOM-RT) standards, 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, and export the information. The product automatically and semi-automatically segments normal structures and abnormal structures (for example, nodules and lesions), and provides metrics for the structures.

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 (for example, image analysis) 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.

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	October 26, 2015
Trade Name	HealthMyne
Classification	Class II per 21 CFR 892.2050 Picture Archiving and Communications System
Product Code	LLZ

Marketed Devices

HealthMyne is a 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 VitreaAdvanced software cleared for marketing via 510(k) K121213 by Vital Images, Inc.

Device Description

HealthMyne 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. The system can automatically segment and register data sets, and calculate metrics on clinician-identified nodules. When a clinician identifies a seed point for a nodule, the system automatically finds the extent of the nodule. Regions of interest (organs and nodules) can be viewed on the 2D data sets as contours and as 3D models. Metrics can be used to aid in analysis of a study, including the American College of Radiology RADS standards, and specifically with this release the LungRADs categories.

Intended Use

The HealthMyne 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 software displays, processes, stores, and transfers medical data from original equipment manufacturers (OEMs) that support the HL7 and DICOM (including DICOM-RT) standards, 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, and export the information. The product automatically and semi-automatically

segments normal structures and abnormal structures (for example, nodules and lesions), and provides metrics for the structures.

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 (for example, image analysis) 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 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	Submission – HealthMyne 2015 Rel 2	Predicate – VitreaAdvanced 6.6 (K121213)
Device Name	HealthMyne	VitreaAdvanced*
510(k) owner	HealthMyne, Inc.	Vital Images, Inc.
Supports mammography	No.	No.
Operating System	Windows, Linux	Windows
Platform	Client-server	Client-server
JPG/JPG 2000	Supported using third-party Kakadu tool. ISO 10918/15444	Supported. See DICOM conformance statement at vitalimages.com.
Images are stored/ compressed/ uncompressed	Both. Lossy used to indicate loading/for display only and lossless loaded simultaneously, unless DICOM contains lossy only.	Both. Users can choose to compress images.
Local archive: Server level/ archive level	No separate archive due to software-only product. Redundant data storage recommended to the customer.	Yes. Available as a separate product.
DICOM compliant	Yes. See conformance statement.	Yes. See conformance statement at vitalimages.com.
HL7 support	Yes. See conformance statement.	No reference to HL7.
Study lists	Yes.	Yes.
Ability to filter and search study list	Yes. Can set up custom filters. Dynamic (freeform) search and matching. Also customizable, indexed search parameters.	Yes. Can set up custom filters. Search and matching.
View study-related documents	Yes. Presentation states and regions of interest/nodules.	Yes. Presentation states and regions of interest/nodules.
Manage pushed studies	Yes. This product supports only pushed studies. No studies originate within this product.	Yes. This product can import and export using DICOM.

Element	Submission – HealthMyne 2015 Rel 2	Predicate – VitreaAdvanced 6.6 (K121213)
View current and prior studies at the same time	Yes. Called current study and prior study. Prior studies have a large "PRIOR" label in each viewport.	Yes. Can select series from different studies for the same patient.
Re-organize series in a study (for viewing)	Yes. Has a thumbnail view with the ability to drag and drop the thumbnail into a viewport. Cannot save the order.	Yes. Can drag and drop a viewport image to another viewport.
Create separate displays	Yes. Can display a viewport as a single viewport, can select a viewport layout and add series to it.	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 manual cine.	Yes. Static and manual cine.
Display color images	Yes.	Yes.
Select images	Yes. There is an active image indicator. The active image can be chosen or is automatically set based on tool use.	Yes. Select images to group and/or perform functions.
Delete images	Yes. Only with PACS admin privileges and from the admin console.	Yes. Can delete images from the viewer window.
Sort images	Yes. Sorting and grouping are by system-defined rules.	Yes. Sorting and grouping are by system-defined rules.
Scrolling through slices	Yes. Linked series are scrolled together. Can "swipe" on a scroll bar to move through slices quickly. Can lock/unlock scrolling through every image.	Yes. Grouped series are scrolled together.
Zoom in/out	Yes. Default settings and can zoom interactively.	Yes. Default settings and can zoom interactively.
Pan an image	Yes.	Yes.
Rotate an image	Yes. In 3D.	Yes. Can flip 2D images and rotate 2D and 3D images.
3D images	Yes.	Yes.
3D MIP	No.	Yes.
Create oblique planes	No.	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	No. Viewport layouts and hanging protocols are factory-default.	Yes. Viewport layouts can be set by the user.

Element	Submission – HealthMyne 2015 Rel 2	Predicate – VitreaAdvanced 6.6 (K121213)
Labels	Yes. There are labels in the viewport for patient, study, and image information.	Yes. There are labels in the viewport for patient, study, and image information.
Orientation labels	Yes.	Yes.
Cross-reference indicator	Yes. There is a cutline in linked viewports to indicate intersection.	No. Use of cross-hair markers.
Location indicator	Yes. There is a cross-hair tool to show a point of interest.	Yes. There is a cross-hair tool to show a point of interest, also used to change the axis in 3D rotation.
View DICOM data	Yes. You can view the DICOM information about the patient, study, and current image.	Yes. You can view the DICOM information about the patient, study, and current image.
Create MPR images	Yes. MPRs from the external source are supported/displayed and can create multi-planar reconstructions of 2D images.	Yes. Can create multi-planar reconstructions of 2D images and set options for display.
Window/level across series	Yes. W/L settings are applied to the active image and any linked images.	Yes. Must group series to link W/L.
Window/level presets	Yes. Factory default.	Yes. Factory defaults and can save window/level settings.
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 create multi-planar reconstructions of 2D images and 3D views of contours.	Yes. Can create multi-planar reconstructions of 2D images and 3D views.
Annotation	Yes. User can display annotations and can add and edit callouts.	Yes. User can display annotations and can add and edit callouts.
Measuring tools	Yes. Pixel intensity/location and ruler.	Yes. Ruler.
Metrics	Yes. Image analysis metrics.	Yes. Image analysis metrics.
ACR RADS categories	Yes. Architecture in place to display RADS categories, initial implementation is for LungRADS.	Yes. References the Fleischner society guidelines. LungRADS's risk stratification is based on the Fleischner society guidelines.
Store presentation states	Yes. Can save certain visualization settings.	Yes. Can save certain visualization settings.
Detect image/patient issues	Yes. Can view patients and studies with errors.	Yes. Can view patients and studies with errors.
Print reports	No.	Yes. Can export and print reports.

Element	Submission – HealthMyne 2015 Rel 2	Predicate – VitreaAdvanced 6.6 (K121213)
Custom hanging protocols	No. Comes with factory-default hanging protocols.	No. Comes with factory-default layouts.
Custom filters	Yes. Can set filters to affect the studies listed.	Yes. Can set filters to affect the studies listed.
Set reading state	Yes. Can mark a study as read.	Yes. Can mark a study as read.
Custom search groups	Yes. Can set "codes" to index elements for searching (for example, referring physician or sets of exam types) for faster auto-complete during search.	Yes. Can set searches using matches and ranges on the column headings.
Display RTP structures	Yes. Supports DICOM RT structures.	Yes. Supports DICOM RT structures.
Register images	Yes. Can automatically and/or manually register images.	Yes. Can manually synchronize datasets in viewers. Only applies to MPRs and 3D images.
Segment regions of interest (ROIs)	Yes. Can automatically generate ROIs and also manually identify nodules for automatic generation of nodule ROIs.	Yes. Can automatically generate ROIs and also manually identify nodules for automatic generation of nodule ROIs.
Edit ROIs	Yes. Can edit the shape of nodules in three dimensions.	Yes. Can edit ROIs in three dimensions.
Manual nodule detection	Yes. Manual click to identify nodules, automatic segmentation of the volume.	Yes. Manual click to identify nodules, automatic segmentation of the volume.
Automatic nodule detection	No.	Yes. Automatic detection of nodules in current study if nodules identified in previous studies, and the reverse.
Nodule display modes	Yes. View nodules independently or in reference to other anatomy.	Yes. View nodules independently or in reference to other anatomy.
Image fusion	No.	Yes. Create a fused 3D image by combining series.
Timeline comparison	No.	Yes. Compare between nodules in studies of elapse time between scans, doubling time, percent growth

Summary of Studies

The HealthMyne 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, HL7 standard for patient information, SMPTE display, and the JPEG2000 image standard.

Conclusion

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