DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 18, 2017

Arterys, Inc.
% Ms. Golnaz Moeini
Director of Quality and Regulatory Affairs
51 Federal Street, Suite 305
SAN FRANCISCO CA 94107

Re: K171544
Trade/Device Name: Arterys Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 24, 2017
Received: May 26, 2017

Dear Ms. Moeini:

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.

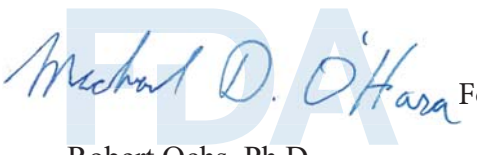
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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)*
K171544

Device Name
Arterys Viewer

Indications for Use *(Describe)*
Arterys Viewer is intended to be used as a Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. The Arterys Viewer displays, processes, stores, and transfers medical data from original equipment manufacturers (OEMs) that support the DICOM 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.

Section 5. 510(k) Summary

1. General Information

510(k) Sponsor	Arterys Inc.
Address	51 Federal St. Suite 305 San Francisco, CA 94107
Correspondence Person	Golnaz Moeini, RAC Director of Quality and Regulatory Arterys Inc.
Contact Information	Email: quality@arterys.com Phone: 408-504-3187
Date Prepared	May 24, 2017

2. Proposed Device

Proprietary Name	*Arterys Viewer*
Common Name	*Viewer*
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

3. Predicate Device

Primary Predicate

Proprietary Name	*HealthMyne PACS*
Premarket Notification	K152186
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

Reference Device

Proprietary Name	*Arterys Software 2.0*
Premarket Notification	K162513
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

4. Device Description

Arterys Viewer is intended to be used as a Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. The Arterys Viewer displays, processes, stores, and transfers medical data from original equipment manufacturers (OEMs) that support the DICOM 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.

The following visualization, quantification and data-reporting functionalities are provided by the software:

Visualization:
- 2D image review
- 3D image review by means of MIP, MinIP, Surface or Average
- Multi-planar reconstruction (MPR) views (axial, coronal, sagittal, and oblique)
- Image navigation tools
- Cine play

Quantification:
- Distance and area measurements

Data reporting:
The distance, area, and user-selected annotated images are displayed to the user within the software client web browser. The user has the option to save the data for later use. The user can also send the data to PACS, for review.

5. Indications for Use

Arterys Viewer is intended to be used as a Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. The Arterys Viewer displays, processes, stores, and transfers medical data from original equipment manufacturers (OEMs) that support the DICOM 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.

6. Comparison of Technological Characteristics with the Predicate and Reference Device

Feature/ Function	**Proposed Device:** Arterys Viewer	**Primary Predicate Device:** HealthMyne PACS (K152186)	**Reference Device:** Arterys Software v2.0 (K162513)
Support Mammography	No	No	
Operating System	Client server architecture using Linux server and web browser client (Web-based only)	Client server architecture utilizing Windows and Linux Platforms (Installed-client only)	Client server architecture using Linux server and web browser client (Web-based only)
Image storage/ compression	Support JPEG2000 and compression	Support JPEG2000 and compression	
DICOM Compliant	Yes	Yes	
Worklists	Yes	Yes	
Filter and Search capabilities	Yes	Yes	
Ability to search studies	Yes	Yes. Dynamic (freeform) search and matching. Also customized, indexed search parameters.	
View study-related documents	Yes. Can view reports/documents (except RT Struct)	Yes. Presentation states and RT Struct (regions of interest)	
Priority "stat" studies	No	Yes. Studies with a DICOM priority tag ("Stat" studies) are given priority order (top of the list) in the exam view.	No
Managed pushed studies	Yes. This product supports only pushed studies. No studies originate within the product	Yes. This product support only pushed studies. No studies originate within the product	
View current and prior studies at the same time	No	Yes. Called current study and prior study. Prior studies have a large "PRIOR" label in each viewport.	No

Feature/ Function	Proposed Device: Arterys Viewer	Primary Predicate Device: HealthMyne PACS (K152186)	Reference Device: Arterys Software v2.0 (K162513)
Re-organize series in a study (for viewing)	Yes	Yes. Has a thumbnail view with the ability to drag and drop the thumbnail into a viewport. Cannot save the order.	
Create separate displays	Yes	Yes. Can display a viewport as a single viewport, can select a viewport layout and add series to it.	
Cycle through series	Yes	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. The images currently being viewed are highlighted, and can be chosen by the user.	Yes. There is an active image indicator. The active image can be chosen or is automatically set based on tool use.	
Delete Images	No	Yes. Only with PACS admin privileges and from the admin console.	No
Sort Images	Yes	Yes. Sorting and grouping are by system-defined rules	
Scrolling through slices	Yes	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 can zoom interactively	Yes. Default settings can zoom interactively	

Feature/ Function	**Proposed Device:** Arterys Viewer	**Primary Predicate Device:** HealthMyne PACS (K152186)	**Reference Device:** Arterys Software v2.0 (K162513)
Pan an image	Yes	Yes	
Standard viewport layouts	Yes	Yes. Viewport layouts that are independent of any modality or common features of series	
Labels	Yes	Yes. There are labels in the viewport for patient, study, and image information.	
Orientation labels	Yes	Yes	
Cross-reference indicator	Yes	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 and study, and the pixel information	
Create MPR images	Yes	No. MPRs from the external source are supported/displayed.	Yes

Feature/ Function	Proposed Device: Arterys Viewer	Primary Predicate Device: HealthMyne PACS (K152186)	Reference Device: Arterys Software v2.0 (K162513)
Window/level determination	Yes Same approach as predicate but we let the user adjust W/L	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 histogram is used.	
Window/level access series	Yes	Yes. W/L settings are applied to the active image and any linked images.	
Window/level presets	Yes	Yes. Factory default	
Adjust window/level	Yes. Can interactively adjust the window and level	Yes. Can interactively adjust the window and level	
Annotation	Yes. Display Only	Yes. Display Only	
Measuring tools	Yes. Linear, area, and pixel intensity and location of a point	No. Pixel intensity and location.	Yes. Linear, area, and pixel intensity and location of a point

Feature/ Function	**Proposed Device:** Arterys Viewer	**Primary Predicate Device:** HealthMyne PACS (K152186)	**Reference Device:** Arterys Software v2.0 (K162513)
Detect image/patient issues	No	Yes. Can view patients and studies with errors	No
Custom filters	Yes. Can set filters to affect the studies listed	Yes. Can set filters to affect the studies listed	
Set reading state	Yes	Yes. Can mark a study as read.	
Custom search groups	Yes	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	No	Yes. Supports DICOM RT Structures	No
Surface Rendering	Yes	No	Yes
Annotation Propagation	Yes	No	Yes

Feature/ Function	Proposed Device: Arterys Viewer	Primary Predicate Device: HealthMyne PACS (K152186)	Reference Device: Arterys Software v2.0 (K162513)
Time Curve Display	Yes	No	Yes
Contour Creation	Yes	No	Yes
Report Creation	Yes	No	Yes

7. Substantial Equivalence Summary

Arterys Viewer has the same intended use, indications for use and technological characteristics as the HealthMyne PACS predicate device (K152186). The added features to allow for usability enhancements is similar to the features in the reference device, *Arterys Software v2.0*, which was cleared by the FDA under K162513. Any noted minor differences have been explained and do not raise any different questions of safety or effectiveness. The implemented design controls, risk management activities, labeling and performed verification and validation tests demonstrate the safety and efficacy of the proposed device. Based on the comparison information provided above, *Arterys Viewer* is substantially equivalent to the predicate device.

8. Performance Data

Safety and performance of *Arterys Viewer* has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software validation activities were performed in accordance with *IEC 62304:2006/AC: 2008- Medical device software – Software life cycle processes,* in addition to the FDA Guidance documents, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* and *"Content of Premarket Submission for Management of Cybersecurity in Medical Devices."*

9. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics and performance testing, *Arterys Viewer* raises no new

questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety, efficacy and performance.