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

October 28, 2016

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

Re: K162513
Trade/Device Name: Arterys Software v2.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 14, 2016
Received: October 21, 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,

Michael D. O'Hara

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)*
K162513

Device Name
Arterys Software v2.0

Indications for Use *(Describe)*
The Arterys Software consists of software that analyzes DI COM-compliant cardiovascular images acquired from magnetic resonance (MR) scanners. Arterys Software specifically analyzes the blood flow to the heart and its major vessels using multi-slice, multi-phase and velocity encoded MR images. It provides clinically-relevant and reproducible, quantitative data, and it has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners. The data produced by the Arterys Software is intended to be used to support qualified cardiologist, radiologist, or other licensed professional healthcare practitioners for clinical decision-making. It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 Director of Quality and Regulatory, RAC Arterys Inc.
Contact Information	Email: golnaz@arterys.com Phone: 408-504-3187
Date Prepared	08/01/2016

2. Proposed Device

Proposed Device:

Proprietary Name	*Arterys Software v2.0*
Common Name	*Arterys Software v2.0*
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

3. Predicate Device

Primary Predicate Device:

Proprietary Name	*Morpheus HeartScan*
Premarket Notification	K133937
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

Secondary Predicate Device:

Proprietary Name	*Medis Imaging QMass*
Premarket Notification	K140587
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

4. Device Description

The *Arterys Software* is a web-accessible image post-processing analysis software device for viewing and quantifying cardiovascular MR images. The device is intended to visualize and quantify MRI data in DICOM format. Manual and semi-automatic border detection forms the basis for the analysis. The software has features for loading, saving, generating screen displays, and aggregating quantitative data from cardiovascular images acquired from magnetic resonance (MR) scanners. The *Arterys Software* is intended for use in both pediatric (neonate, infant, child and adolescent) and adult populations.

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

Visualization:

- 2D image review
- 3D image review by means of MIP, Surface MinIP, Surface and Average
- Multi-planer reconstruction (MPR) views (axial, coronal and sagittal)
- Image navigation tools
- Cine play
- Cardiac view

Quantification:

- Anatomy and tissue segmentation
- Linear distance and area measurements
- Flow quantification, including net flow, forward flow, reverse flow, regurgitation fraction, pressure gradient and primary flow direction, at user-specified locations where contours have been created (i.e. aortic valve, pulmonary valve, mitral valve, tricuspid valve, and superior vena cava).
- Cardiac function volume quantification including stroke volume, ejection fraction, cardiac output, end-diastolic mass and volume, end-systolic mass and volume
- Phase correction

Data reporting:

The volume, blood flow and linear distance statistics, along with 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 the clinician database, such as PACS, for review.

5. Indications for Use

The *Arterys Software* consists of software that analyzes DICOM-compliant cardiovascular images acquired from magnetic resonance (MR) scanners. *Arterys Software* specifically analyzes the blood flow to the heart and its major vessels using multi-slice, multi-phase and velocity encoded MR images. It provides clinically-relevant and reproducible, quantitative data, and it has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners. The data produced by the *Arterys Software* is intended to be used to support qualified cardiologist, radiologist, or other licensed professional healthcare practitioners for clinical decision-making. It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.

6. Comparison of Technological Characteristics with the Predicate Device

Feature/ Function	**Proposed Device:** Arterys Software	**Primary Predicate Device:** Morpheus HeartScan (K133937)	**Secondary Predicate Device:** Medis Imaging QMass (K140587)
Operating System	Linux	Linux	Not Applicable
Platform	Client-server, Chrome Desktop	Client-server, Chrome Desktop	Not Applicable
Scanners	Both 1.5T and 3.0T	Both 1.5T and 3.0T	Not Applicable
Image input	Supports DICOM 3.0	Supports DICOM 3.0	Not Applicable
Data acquisition protocol for flow and volume analysis	Cardiovascular images: multi-phase, multi-slice and velocity encoded images acquired from MRI scanners	Cardiovascular images: multi-phase, multi-slice and velocity encoded images acquired from MRI scanners	Not Applicable
Image display mode	Static and cine	Static and cine	Not Applicable
Image Navigation Tools[1]	Pan, zoom, rotate, maximize/minimize, slice scroll (view multiple slices), adjust window/level, slab thickness, flow direction and time scroll (view multiple	Pan, zoom, rotate, maximize/minimize, slice scroll (view multiple slices), adjust window/level, time scroll (view multiple phases), image ROI placement;	Not Applicable

Feature/ Function	**Proposed Device:** Arterys Software	**Primary Predicate Device:** Morpheus HeartScan (K133937)	**Secondary Predicate Device:** Medis Imaging QMass (K140587)
	phases), image ROI placement; automated 2D ROI (with edit functions); 2D speed color map.	automated 2D ROI (with edit functions); 2D speed color map.	
2D image review	Yes	Yes	Not Applicable
3D (volume rendered) image review	Yes	Yes	Not Applicable
Cardiac View[2]	Yes	No	Not Applicable
Orientation label	Yes	Yes	Not Applicable
Cross-reference indicator[3]	Yes	No	Not Applicable
View DICOM data	Yes, users can view the DICOM information about the patient, study and current image	Yes, users can view the DICOM information about the patient, study and current image	Not Applicable
Secondary Capture[4]	Yes	No	Not Applicable
Segmentation of region of interest	Manual and semi-automatic	Manual and semi-automatic	Not Applicable
Phase error correction	Yes, Eddy Current Correction	Yes, Eddy Current Correction	Not Applicable
Quantitative Analysis, flow	Yes	Yes	Not Applicable
Quantitative Analysis, area	Yes	Yes	Not Applicable

Feature/ Function	Proposed Device: Arterys Software	Primary Predicate Device: Morpheus HeartScan (K133937)	Secondary Predicate Device: Medis Imaging QMass (K140587)
Quantitative Analysis, linear distance[5]	Yes	Yes	Not Applicable
Quantitative Analysis, volume	Yes	Not Applicable	Yes
2D Phase Contrast[6]	Yes	No	Not Applicable
Directional/vector display of the blood particle travel[8]	Blood flow and flow direction are available by means of color overlay and vectors and/or streamlines	Blood flow is available by means of color overlay. Vector component information is displayed.	Not Applicable
Flow quantification of valves[9]	Option to adjust plane at each Timepoint for flow measurement. Same flow algorithm as predicate.	Flow measurement in a static plane, with the option to create a separate flow measurement at different planes for each Timepoint.	Not Applicable
Automatic selection of the Temporal Landmark Timepoints[10]	Available as a prerequisite step to volume measurement.	Not Applicable	Available as a prerequisite step to volume measurement.

7. Performance Data

Safety and performance of the *Arterys Software* has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing, as well as software usability 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."*

8. Conclusion

Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, performance testing and technological comparison to the predicate devices, the *Arterys Software* raises no new questions of safety and effectiveness and is substantially equivalent to the predicate devices in terms of safety, efficacy and performanc