Arterys Inc.
Sharon Cholowsky
Director of Regulatory and Compliance
51 Federal Street, Suite 305
SAN FRANCISCO, CA 94107

October 17, 2018

Re: K182034
Trade/Device Name: Arterys MICA
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 22, 2018
Received: September 25, 2018

Dear Sharon Cholowsky:

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,

Michael D. O'Hara 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)*

K182034

Device Name
Arterys MICA

Indications for Use *(Describe)*

Arterys® MICA software is a medical diagnostic application that displays, processes, stores, and transfers DICOM and non-DICOM medical data, with the exception of mammography. It provides the capability to store images and patient information, and perform filtering, digital manipulation, and quantitative measurements. The client software is designed to run on standard personal and business computers.

Arterys MICA includes an optional Cardio AI module which is used to analyze the heart and its major vessels using multi-slice, multi-phase, and velocity-encoded cardiovascular magnetic resonance (MR) images. It provides clinically relevant and reproducible, quantitative data, and has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners.

Arterys MICA includes an optional Oncology AI module which provides analytical tools to help the user assess and document changes in morphological activity at diagnostic and therapy follow-up examinations. It is a tool used to support the oncological workflow by helping the user confirm the absence or presence of lesions, including evaluation, quantification, follow-up, and documentation of any such lesions.

Arterys MICA software is intended to be used as a support tool by trained healthcare professionals to aid in diagnosis. 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	Sharon Cholowsky
Contact Information	Email: regulatory@arterys.com Phone: 403-923-9688
Date Prepared	July 26, 2018

Proposed Device

Proprietary Name	*Arterys® MICA*
Common Name	MICA
Model Number	AMM5
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

Predicate Devices

Primary Predicate Device	*Arterys Viewer,* K171544
Secondary Predicate Device	*Arterys Cardio DL*, K163253
Tertiary Predicate Device	*Arterys Oncology DL*, K173542

2. Device Description

Arterys MICA is a dedicated software application used as a Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. *Arterys MICA* can also be used for analyzing multi-slice and multi-phase computed tomography (CT) or magnetic resonance (MR) image. Pre-existing CT or MR images are uploaded into *Arterys MICA* in a DICOM format from PACS or a scanner. The software has two components: i) client, and ii) server. The client software (i) can be used in a Chrome desktop web browser. The server software (ii) runs on the Linux operating system.

The basic image *Viewer* application of *Arterys MICA* is designed around a modular architecture of separate components that make up the basic image *Viewer*. These components include

the *Worklist*, from which studies are selected and opened, the *Uploads* list that displays all uploaded studies for the current organization and the basic image *Viewer* itself, which allows for viewing and working with 2D and 3D images.

Functionality provided by the basic image *Viewer* is extended by additional *Cardio AI* and *Oncology AI* application modules and can add support for specific clinical workflows. The *Cardio* module adds support for flow-4D studies and provides additional functionality specific to cardiac studies. The *Oncology* module adds functionality specific to evaluating and measuring lesions, including lung and liver lesions/nodules.

NOTE: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of images. Arterys MICA software is a complement to these standard procedures.

3. Indications for Use

Indications for Use Statement for *Arterys MICA* with optional *Cardio* and *Oncology* modules:

> *Arterys® MICA* software is a medical diagnostic application that displays, processes, stores, and transfers DICOM and non-DICOM medical data, with the exception of mammography. It provides the capability to store images and patient information, and perform filtering, digital manipulation, and quantitative measurements. The client software is designed to run on standard personal and business computers.
>
> *Arterys MICA* includes an optional *Cardio AI* module which is used to analyze the heart and its major vessels using multi-slice, multi-phase, and velocity-encoded cardiovascular magnetic resonance (MR) images. It provides clinically relevant and reproducible, quantitative data, and has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners.
>
> *Arterys MICA* includes an optional *Oncology AI* module which provides analytical tools to help the user assess and document changes in morphological activity at diagnostic and therapy follow-up examinations. It is a tool used to support the oncological workflow by helping the user confirm the absence or presence of lesions, including evaluation, quantification, follow-up, and documentation of any such lesions.
>
> *Arterys MICA* software is intended to be used as a support tool by trained healthcare professionals to aid in diagnosis. 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 Indications for Use Statement is a unification of the statements of the three previously cleared devices. The first and fourth paragraphs contain information about the base image *Viewer* as well as information that is applicable for all three areas of the product, while the second and third paragraphs contain information about the *Cardio* module and *Oncology* module, respectively. This unification is because of the similar architecture and device use case of the three cleared products. The intended use is the same between the predicates and new products and there are no new diagnostic claims involved in the wording change.

4. Comparison of Technological Characteristics with the Predicate Device

The *Arterys MICA* software has the same technological characteristics as the predicate Arterys devices and has the same uses and applications as the predicate devices. There have been incremental minor updates to some of the software features for user experience improvements; these software changes do not impact safety or efficacy of the device. Both the device and predicates are used by the clinician as a support tool to aid in diagnosis of radiological images.

Table 5.1: Technological characteristics of the proposed device and predicate devices

Feature/ Function	**Proposed Device** ***Arterys MICA***	**Primary Predicate** ***Arterys Viewer*** **(K171544)**	**Secondary Predicate** ***Arterys Cardio DL*** **(K163253)**	**Tertiary Predicate** ***Arterys Oncology DL*** **(K173542)**
Ability to load different optional modules from same worklist	Yes - all three modules are in drop down menu	No - Cardio module included in Viewer	No - Module included in Viewer	No - Module loaded separately
Operating System	Client server architecture using Linux server and web browser client	Same	Same	Same
Image storage/ compression	Support JPEG2000 and compression	Same	Same	Same
DICOM compliant	Yes	Same	Same	Same
Type of scans/ Modality	Viewer: MR, CT Cardio: MR Onco: MR and CT	Same	Same	Same
Worklist with filter and searching	Yes. Added tags for further identification.	Yes.	N/A	N/A
Image upload	Yes	Same	N/A	N/A

2D, 3D, MIP, MPR image display	Yes	Same	Same	Same
Cine play	Yes	Same	Same	Same
Image navigation tools	Pan, zoom, rotate, maximize/minimize, slice scroll (view multiple slices), adjust window/level, slab thickness, time scroll (view multiple phases)	Same	Same	Same
Image navigation - Cardio	Yes. Flow direction and 2D speed color map	N/A	Same	N/A
Image layouts; side-by-side viewing	Yes. Added multi-study and that images are now commonly aligned.	Yes.	Yes.	Yes.
View DICOM data	Patient, study, orientation, and pixel information	Same	Same	Same
Measuring tools	Yes - linear, area, and volume for all three modules.	Yes - linear and area only.	Yes - linear and area only.	Yes - linear, area, and volume.
Semi-automated segmentation of region of interest	Yes. Cardio and Oncology only.	No	Yes	Yes
Cardio - identification of landmarks	Yes - Automatically identified + user editable	N/A	Yes - Manually identified + editable	N/A
Cardio Visualization, Quantification, Volume in 4D Flow	Yes. Added normalized volume measurements based on age and gender. Added ability to edit the valve plane to adjust volume.	N/A	Yes	N/A
Cardio - 2D Contour inference	Yes - Automatically identified + user editable. Added ability to edit the valve plane to adjust volume.	N/A	Yes - Manually identified + editable	N/A
Cardio Visualization, Quantification, Volume in 3D Workflow for a short axis stack	Yes. Added normalized volume measurements based on age and gender. Added ability to edit the valve plane to adjust volume.	N/A	Same	N/A

Eddy current correction	Yes. Added ability to download data.	N/A	Same	N/A
Cardio Reporting	Yes. Added minimal content configurability.	N/A	Yes	N/A
Co-registration	Yes	N/A	N/A	Same
Onco Longitudinal tracking - linked VOIs between timepoints	Yes	N/A	N/A	Same
Onco Reporting - LI-RADS and Lung-RADS	Yes	N/A	N/A	Same
Secondary Capture	Yes	Same	Same	Same
Download report	Yes - to PACS and computer	Yes - to PACS only	N/A	N/A

5. Performance Data

Safety and performance of *Arterys MICA* has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Additionally, the software verification and validation activities were performed in accordance with *IEC 62304:2006/AC: 2015- Medical device software – Software life cycle processes* and *ISO 14971:2007 Medical devices -- Application of risk management to medical devices,* 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."*

6. Conclusion

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