March 14, 2022

Arterys Inc.
% Marina Codari
Head of Clinical Evidence
51 Federal Street, Suite 305
SAN FRANCISCO CA 94107

Re: K203744
Trade/Device Name: Arterys MICA
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: February 8, 2022
Received: February 11, 2022

Dear Marina Codari:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K203744

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. 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 and on monitors/screens that meet appropriate technical specifications for image diagnosis.

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.

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

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Traditional 510(k) Premarket Notification

for

Arterys® MICA

K203744/S002

Arterys Inc.
2100 Fillmore Street #100, San Francisco, CA 94115, U.S.A

Section 5. 510(k) Summary

510(k) Summary

1. General Information

Date Prepared: December 17, 2020
Date Updated: March 08, 2022

Submitter Information

Company Name	Arterys Inc.
Company Address	2100 Fillmore Street #100, San Francisco, CA 94115, U.S.A
Contact Person	**John Axerio-Cilies** CEO and CTO
Contact Information	Email: regulatory@arterys.com Phone: 1 (650) 391-7111

Proposed Device

Proprietary Name	*Arterys® MICA*
Common Name	Medical image processing software
Model Number	AMM7
Regulation Number	21 CFR 892.2050 Medical image management and processing system
Product Code	QIH/LLZ
Regulatory Class	II

Predicate Device

Predicate Device	*Arterys® MICA*, K192437 Product Code QIH/LLZ

2. Device Description

Arterys MICA, already cleared as per the predicate, is a dedicated software application used as a Digital Imaging and Communications in Medicine (DICOM) and non-DICOM information and data management system. Pre-existing DICOM images, such as CT or MR, are uploaded into *Arterys MICA* from a PACS or a scanner. *Arterys MICA* is completely hosted in the cloud and is accessed using a compatible web browser by navigating to the following https://app.arterys.com. Cloud servers are provided by Amazon Web Services (AWS) and service is accessible globally.

The *Viewer AI* application of *Arterys MICA* is designed around a modular architecture of separate components that make up a basic image viewer. These include the Studylist, from which studies are selected and opened, the image display (2D, 3D, MIP, etc), view synchronization, metadata information, and various navigational, measurement, and other action tools.

Functionality provided by the *Viewer AI* is extended by the additional *Cardio AI* and *Oncology AI* application modules which add support for specific clinical workflows:

- Cardiac Workflow Module: Evaluates multi-slice and multi-phase velocity-encoded cardiovascular magnetic resonance (MR) images to quantify blood flow and ventricular function. In addition, perfusion and delayed enhancement datasets are analyzed and quantified, and for parametric mapping, T1, T2, and T2* values are obtained to assess tissue changes in the myocardium, as well as ECV calculations.
- 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 uses many deep learning algorithms to reduce many tedious, time-consuming manual steps, such as segmentation, landmark identification, etc. The results of these AI models are available on-screen to the user for further review and editing. The software does not perform any functions that could not be accomplished by a trained user with a manual method; the purpose of the automation is to save time and automate potential error-prone manual tasks, while allowing the results to be reviewed as per the normal clinical workflow.

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* is as follows:

Arterys® *MICA* software is a medical diagnostic application that displays, processes, stores, and transfers DICOM and non-DICOM medical data. 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 and on monitors/screens that meet appropriate technical specifications for image diagnosis.

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 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.

4. Predicate Device Comparison

The indications for use of the proposed device *Arterys MICA* is similar to the predicate device. They are intended to be used as a support tool by trained healthcare professionals to aid in diagnosis. The devices are intended to provide image and related information that is interpreted by a trained professional to render findings and/or diagnosis.

The indications for use of the proposed device consists of the indications for use statement of the predicate, *Arterys MICA* (K192437). The differences in the added indications for use are mainly due to duplication with other phrases in the existing *Arterys MICA* (K192437) indications for use statement and don't raise different questions of safety and effectiveness.

The ability of Viewer AI to display annotations (segmentation, measurements, etc.) was expanded to integrate similar outputs of 3rd party models (bounding boxes, heatmaps, etc.). The safety and effectiveness of the 3rd party model is covered under the original manufacturer's regulatory clearance; Arterys only displays the simple output.

The cardiac MRI T1 and T2 workflows were added to the proposed Cardio AI product. The workflows and feature lists are in alignment with the SCMR (Society for Cardiovascular Magnetic Resonance) Post Processing Consensus Statement (https://scmr.org/page/guidelines). The workflows and calculations are based on published industry technical standards and peer-reviewed publications, resulting in no different questions of safety and effectiveness.

The *Arterys MICA* software has the similar technological characteristics as the predicate device and has the same uses and applications as the predicate device. Differences include minor incremental updates to some of the existing software features for user experience improvements. These software changes do not impact safety or efficacy of the device.

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. The software verification and validation activities were performed as per *IEC 62304:2006/AC:2015- Medical device software – Software life cycle processes* and *ISO 14971:2019 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.*

Hundreds of software verification and validation tests were repeatedly conducted throughout the software development effort, with any defects logged and traced to the failed tests. Defects were then fixed or were assessed for approval in the released product.

In our validation assessment, we compared the average T1 and T2 values obtained with the Arterys software in delineated regions of interest (ROIs) to the average intensity value obtained in a similar ROI delineated in OEM vendor generated inline maps. The results showed that the difference between calculated and expected T1 and T2 values were within predefined accuracy requirements (i.e., 30 ms and 4 ms for T1 and T2 values, respectively). T1 and T2 values derived with the Arterys software depends on the ROI selected by the user.

In the T1 workflow, endocardial and epicardial contours can be generated using a deep learning model. The generated contours are user-modifiable. These contours are used to derive Global T1 values. A standalone performance assessment was performed on 90 Cardiac T1 Mapping MRI short axis (SAX) scans from 16 studies. As a result, the device performed as intended compared to ground-truth contours.

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