January 25, 2018

Arterys Inc.
% Mr. John Axerio-Cilies
Chief Operating Officer and Founder
51 Federal Street, Suite 305
SAN FRANCISCO CA 94107

Re: K173542
Trade/Device Name: Arterys Oncology DL
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 15, 2017
Received: November 16, 2017

Dear Mr. Axerio-Cilies:

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.

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.

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 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)*

K173542

Device Name
Arterys Oncology DL

Indications for Use *(Describe)*

Arterys Oncology DL is a medical diagnostic application for viewing, manipulation, 3D- visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MIP and volume rendering.

Arterys Oncology DL enables visualization of information that would otherwise have to be visually compared disjointedly. Arterys Oncology DL provides analytical tools to help the user assess and document changes in morphological activity at diagnostic and therapy follow-up examinations.

Arterys Oncology DL is designed 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.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. Arterys Oncology DL is a complement to these standard procedures.

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.

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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	John Axerio-Cilies COO and Founder
Contact Information	Email: quality@arterys.com Phone: 650-391-7111
Date Prepared	Nov. 15, 2017

2. Proposed Device

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

3. Predicate Device

Proprietary Name	*syngo™ TrueD*
Premarket Notification	K101749
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

4. Reference Device

Proprietary Name	*Arterys Cardio DL*
Premarket Notification	K163253
Classification Name	System, Image Processing, Radiological
Regulation Number	21 CFR 892.2050
Product Code	LLZ
Regulatory Class	II

5. Device Description

This traditional 510(k) is being submitted for *Arterys Oncology DL* which is intended for viewing, manipulation, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MIP and volume rendering. The software supports the oncological workflow by helping the user to

confirm the absence or presence of lesions, including evaluation, quantification, follow-up and documentation of any such lesions.

Key features of the software are:

- 2D and 3D visualization and comparative review
- Manual volumetric segmentation
- Semi-automatic volumetric segmentation of lung nodules and liver lesions
- Co-registration
- Longitudinal tracking
- Nodule/lesion size quantifications
- Data reporting based on Lung-RADS and LI-RADS guidelines

6. Indications for Use

Arterys Oncology DL is a medical diagnostic application for viewing, manipulation, 3D-visualization and comparison of medical images from multiple imaging modalities and/or multiple time-points. The application supports anatomical datasets, such as CT or MR. The images can be viewed in a number of output formats including MIP and volume rendering.

Arterys Oncology DL enables visualization of information that would otherwise have to be visually compared disjointedly. *Arterys Oncology DL* provides analytical tools to help the user assess and document changes in morphological activity at diagnostic and therapy follow-up examinations.

Arterys Oncology DL is designed 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.

Note: The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of the separate unregistered images. *Arterys Oncology DL* is a complement to these standard procedures.

7. Comparison of Technological Characteristics with the Predicate Device

Table 5.1: Comparison Table

Feature/ Function	**Proposed Device:** *Arterys Oncology DL*	**Predicate Device (Primary):** *syngo™ TrueD* (K101749)	**Reference Device:** *Arterys Cardio DL* **(**K163253)
Image input	Complies with DICOM Standard	Complies with DICOM & DICOM RT Standards	
Type of scans	MR, CT	MR, CT, PET, SPECT	

Feature/ Function	**Proposed Device:** *Arterys Oncology DL*	**Predicate Device (Primary):** *syngo™ TrueD* (K101749)	**Reference Device:** *Arterys Cardio DL* **(**K163253)
2D and 3D Image Review	Yes	Yes	
2D and 3D Comparative Review	Yes	Yes	
Manual-Volumetric Segmentation	Yes	Yes	
Co-registration	Yes	Yes	
Longitudinal Tracking	Yes, linked VOIs between timepoints	Yes, linked VOIs between timepoints	
Linear Dimension Calculation for Volumetric Segmentation	Yes, longest linear dimension (mm) in axial plane, and orthogonal to longest linear dimension	Yes, maximum diameter (mm) measurement	
Volume Calculation	Yes	Yes	
Reporting	Yes, basic reporting and LI-RADS and Lung-RADS observation reporting based on standard guidelines	Yes, basic reporting	
Semi-automated, Volumetric Segmentation	Yes, available only for lung CT and liver MR studies		Yes, available for ventricular segmentation

8. Performance Data

The safety and performance of Arterys Oncology DL has been evaluated and verified in accordance with software specifications and applicable performance standards through software verification and validation testing. Non-clinical verification and validation test results established that the device meets its design requirements and intended use, that it is as safe and

as effective as the predicate devices, and that no new issues of safety and effectiveness were raised. Arterys non-clinical V&V testing included Testing for Liver MR Deep Learning Model, Lung MR Deep Learning Model, Lung Longitudinal Tracking and usability. The Verification, validation and usability testing data demonstrate that the device meets all its specifications.

Further, during the development, potential hazards were controlled by a risk management plan including risk analysis, risk mitigation, verification and risk-benefit analysis. Additionally, the software verification and validation activities were performed in accordance with the following standards, in addition to the FDA Guidance Document, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"*:

- Digital Imaging and Communications in Medicine (DICOM); PS 3.1 - 3.20 (2011)
- Medical device software - Software life cycle process, IEC 62304; First edition 2006-05, 2015
- Medical devices - Application of risk management to medical devices, ISO 14971; Second edition 2007-03-01, 2012
- Medical Devices - Application of usability engineering to medical devices, ISO 62366: 2007/(R) 2013

9. Conclusion

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