



August 20, 2025

Artrya Limited
Gabriela Quijada
Quality and Regulatory Manager
1257 Hay Street
West Perth
Perth, WA 6005
Australia

Re: K251837

Trade/Device Name: Salix Coronary Plaque (V1.0.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: June 16, 2025
Received: June 16, 2025

Dear Gabriela Quijada:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

Jessica Lamb

Assistant Director, Imaging Software Team

DHT8B: Division of Radiologic Imaging

Devices and Electronic Products

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K251837

Device Name
Salix Coronary Plaque (V1.0.0)

Indications for Use (Describe)

Salix Coronary Plaque (V1.0.0) is a web-based, non-invasive software application that is intended to be used for viewing, post-processing, and analyzing cardiac computed tomography (CT) images acquired from a CT scanner in a Digital Imaging and Communications in Medicine (DICOM) Standard format.

This software provides cardiologists and radiologists with interactive tools that can be used for viewing and analyzing cardiac computed tomography (CT) data for quantification and characterization of coronary plaques (i.e. atherosclerosis), stenosis and to perform calcium scoring in non-contrast cardiac CT

Salix Coronary Plaque (V1.0.0) is intended to complement standard care as an adjunctive tool and is not intended as a replacement to a medical professional's comprehensive diagnostic decision-making process. The software's semi-automated features are intended for an adult population and should only be used by qualified medical professionals experienced in examining and evaluating cardiac CT images.

Users should be aware that certain views make use of interpolated data. These data are created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

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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K251837

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: June 15, 2025

Submitter: Artrya Ltd.

Official Contact: Gabriela Quijada
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West Perth, 6005, Australia
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Secondary Contacts: Richard M. Stewart, Ph.D.
1230 Rosecrans Ave, Suite 300, PMB 713
Manhattan Beach, CA 90266
Phone: +1 415-735-4165

Proprietary Name: Salix Coronary Plaque (V1.0.0)

Common Name: Automated Radiological Image Processing Software System, Image Processing, Radiological

Classification: Class II Medical Device
Regulation Number: 21 CFR 892.2050
Product Codes: QIH, LLZ

Predicate Devices: CaRi-Plaque (K242240) - Primary
Salix Central (K243038) - Secondary

Reason For Submission: New Traditional 510(k)

Indications for Use

Salix Coronary Plaque (V1.0.0) is a web-based, non-invasive software application that is intended to be used for viewing, post-processing, and analyzing cardiac computed tomography (CT) images acquired from a CT scanner in a Digital Imaging and Communications in Medicine (DICOM) Standard format.

This software provides cardiologists and radiologists with interactive tools that can be used for viewing and analyzing cardiac computed tomography (CT) data for quantification and characterization of coronary plaques (i.e. atherosclerosis), stenosis and to perform calcium scoring in non-contrast cardiac CT

Salix Coronary Plaque (V1.0.0) is intended to complement standard care as an adjunctive tool and is not intended as a replacement to a medical professional's comprehensive diagnostic decision-making process. The software's semi-automated features are intended for an adult population and should only be used by qualified medical professionals experienced in examining and evaluating cardiac CT images.

Users should be aware that certain views make use of interpolated data. These data are created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.

Device Description

Salix Coronary Plaque (K251837) is a web-based software application, hosted on Amazon Web Services cloud computing services, delivered using a SaaS model. The software provides interactive, post-processing tools for trained radiologists or cardiologists for viewing, analyzing, and characterizing cardiac computed tomography (CT) image data obtained from a CT scanner. The physician-driven coronary analysis is used to review CT image data to prepare a standard coronary report that may include the presence and extent of physician-identified coronary plaques (i.e., atherosclerosis) and stenosis, and assessment of calcium score performed on a non-contrast cardiac CT scan. The Cardiac CT image data are physician-ordered and typically obtained from patients who underwent CCTA or CAC CT for evaluation of CAD or suspected CAD.

Substantial Equivalence Discussion

Salix Coronary Plaque (SCP) is substantially equivalent to the primary and secondary predicates CaRi-Plaque (K242240) and Salix Central (K241038), respectively. The primary and secondary predicates are differentiated by study analysis and calcium scoring tools, which are reflected in the subject device. Both subject and predicate devices have the same Intended Use/Indications for Use and are similar with respect to key features and performance characteristics as shown in the Predicate Device Comparison Table below:

Predicate Device Comparison			
Topic	Proposed Device	Primary Predicate Device	Secondary Predicate Device
Manufacturer	Artrya Ltd.	Caristo	Artrya Ltd.
Model Name	Salix Coronary Plaque (V1.0.0)	CaRi-Plaque	Salix Central
510(k) Number	Subject Device: K251837	K242240	K243038
Intended Use / Indications for Use	<p>Salix Coronary Plaque (V1.0.0) is a web-based, non-invasive software application that is intended to be used for viewing, post-processing, and analyzing cardiac computed tomography (CT) images acquired from a CT scanner in a Digital Imaging and Communications in Medicine (DICOM) Standard format.</p> <p>This software provides cardiologists and radiologists with interactive tools that can be used for viewing and analyzing cardiac computed tomography (CT) data for quantification and characterization of coronary plaques (i.e. atherosclerosis), stenosis and to perform calcium scoring in non-contrast cardiac CT</p> <p>Salix Coronary Plaque (V1.0.0) is intended to complement standard care as an adjunctive tool and is not intended as a replacement to a medical professional's comprehensive diagnostic decision-making process. The software's semi-automated features are intended for an</p>	<p>CaRi-Plaque is intended to provide an optimized non-invasive application to analyze coronary anatomy and pathology and aid in determining treatment paths from a set of Computed Tomography (CT) Angiographic images.</p> <p>CaRi-Plaque is a web-based image processing application. It is a non-invasive diagnostic reading software intended for use as an interactive tool for viewing and analyzing cardiac CT data for determining the presence and extent of coronary plaques and luminal stenoses.</p> <p>CaRi-Plaque is intended for use by internal operators who have been appropriately trained in the software's functions, capabilities and limitations.</p> <p>Users should be aware</p>	<p>Salix Central is a web-based software application that is intended to be used for viewing, post-processing, and analyzing cardiac computed tomography (CT) images acquired from a CT scanner in a Digital Imaging and Communications in Medicine (DICOM) Standard format.</p> <p>This software provides tools that can be used for the qualitative and quantitative assessment of physician-identified coronary plaques and stenosis in coronary computed tomography angiography (CCTA) and to perform calcium scoring in non-contrast cardiac CT.</p> <p>Salix Central is intended to complement standard care as an adjunctive tool and is not intended as a replacement to a medical professional's comprehensive diagnostic decision-making process. The software's semi-</p>

Predicate Device Comparison			
Topic	Proposed Device	Primary Predicate Device	Secondary Predicate Device
Manufacturer	Artrya Ltd.	Caristo	Artrya Ltd.
Model Name	Salix Coronary Plaque (V1.0.0)	CaRI-Plaque	Salix Central
510(k) Number	Subject Device: K251837	K242240	K243038
	<p>adult population and should only be used by qualified medical professionals experienced in examining and evaluating cardiac CT images.</p> <p>Users should be aware that certain views make use of interpolated data. These data are created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology that is near or smaller than the scanning resolution may be present.</p>	<p>that certain views make use of interpolated data. This is data that is created by the software based on the original data set. Interpolated data may give the appearance of healthy tissue in situations where pathology may be present that is near or smaller than the scanning resolution.</p> <p>The analysis results produced by the software and provided to the Healthcare Professional are not intended to replace the skill and judgment of a qualified medical practitioner. The analysis results should be reviewed with other clinical information which may include but is not limited to: The patient's original CT images, clinical history, symptoms, clinical risk factors, results of other diagnostic tests, and the clinical judgement of appropriately qualified Healthcare Professionals.</p>	<p>automated features are intended for an adult population and should only be used by qualified medical professionals experienced in examining and evaluating cardiac CT images.</p>
Device Class	Class II	Class II	Class II
Product Code	LLZ, QIH	LLZ	QIH
Intended Users	Cardiologists, Radiologists and Clinical Specialists	Cardiologists and Radiologists	Cardiologists, Radiologists and Clinical Specialists
Operating Platform	Client-Server Google Chrome Application	Client-Side Google Chrome Application	Client-Server Google Chrome Application
Stand-alone Software	Yes	Yes	Yes

Predicate Device Comparison			
Topic	Proposed Device	Primary Predicate Device	Secondary Predicate Device
Manufacturer	Artrya Ltd.	Caristo	Artrya Ltd.
Model Name	Salix Coronary Plaque (V1.0.0)	CaRI-Plaque	Salix Central
510(k) Number	Subject Device: K251837	K242240	K243038
DICOM Compliant	Yes; DICOM 3.0 or higher	DICOM 3	Yes; DICOM 3.0 or higher
Image Acquisition	CT	CT	CT
Secured Network Server Integration	Yes	Yes	Yes
Store Images	Yes	Yes	Yes
2D Imaging	Yes	Review of coronary vessels in 2D MPR, curved MPR, and straightened view.	Yes
2D Measurement	Similar	2D measurement tools of vessel diameter and contour	Similar
3D Imaging	Review of structures in 3D	Same	Same
Maximum Intensity Projection (MIP)	Yes; this visualization method not necessary for analyzing the presence and extent of coronary plaque and stenosis	N/A; this visualization method is not necessary for analyzing the presence and extent of coronary plaque and luminal stenosis	Yes
Multiplanar Reformat (MPR)	Yes, MPR with oblique slicing and variable slab thickness is not necessary analyzing the presence and extent of coronary plaque and luminal stenosis	MPR with oblique slicing and variable slab thickness is not necessary analyzing the presence and extent of coronary plaque and luminal stenosis	Yes
Study Analysis – Navigation Tools	Panning Windowing Zooming Series, slices, and phases	Similar	Panning Windowing Zooming Series, slices, and phases
Study Analysis – Visualization and Editing	Centerline Wall Signal Intensity Overlay	Similar	Centerline Wall Signal Intensity Overlay
Measurements	Distance & Area	Area	Distance & Area
Centerline Extraction and Wall Segmentation	Manual and semi-automatic / user-editable	Similar	Manual and semi-automatic / user-editable
Calcium Scoring	Yes	No	Yes
Reporting	Yes	Similar	Yes
Quantitative Measurements			
NCP volume: non-calcified plaque volume	Yes	Yes	Yes

Predicate Device Comparison			
Topic	Proposed Device	Primary Predicate Device	Secondary Predicate Device
Manufacturer	Artrya Ltd.	Caristo	Artrya Ltd.
Model Name	Salix Coronary Plaque (V1.0.0)	CaRi-Plaque	Salix Central
510(k) Number	Subject Device: K251837	K242240	K243038
CP volume: calcified plaque volume	Yes	Yes	Yes
LD-NCP volume: low-density noncalcified plaque volume	Yes	Yes	Yes
Total Plaque Volume	Yes	Yes	No
Vessel Volume	No. This is calculated but not reported as a device output.	No. This is calculated but not reported as a device output.	No
Total plaque burden: total plaque volume/analyzed vessel volume	Yes	Yes	No
NCP burden: noncalcified plaque volume/analyzed vessel volume	Yes	No	No
LD-NCP burden: low-density noncalcified plaque volume /analyzed vessel volume	Yes	No	No
CP burden: calcified plaque volume/analyzed vessel volume	Yes	No	No
Plaque composition Category (Noncalcified plaque, Calcified plaque, Mixed plaque)	Yes	No	No
QCAD: Maximal diameter stenosis, with respect to proximal and distal reference	Yes; Similar (categorical), Manual & Editable*	Yes, refers to a single reference	Yes; Similar, Manual & Editable
Area stenosis:	No; Calculated based on	Yes	No

Predicate Device Comparison			
Topic	Proposed Device	Primary Predicate Device	Secondary Predicate Device
Manufacturer	Artrya Ltd.	Caristo	Artrya Ltd.
Model Name	Salix Coronary Plaque (V1.0.0)	CaRi-Plaque	Salix Central
510(k) Number	Subject Device: K251837	K242240	K243038
maximum area stenosis, with respect to proximal and distal references	diameter stenosis		
Semi-Automated CAD RADS Stenosis: Maximal diameter stenosis, with respect to proximal and distal reference	Yes, Editable	No	No, Manual & Editable
Remodeling index: ratio of maximum vessel area/proximal and distal references	No, Presence/absence of positive remodeling as a classifier	Yes	No
Plaque length: diseased vessel length	No	Yes	No
Contrast density difference: maximum difference in contrast density over lesion with respect to proximal reference	No	Yes	No
MLD: minimal luminal diameter over lesion	No (categorized stenosis only into CAD RADS)	No. This is calculated but not reported as a device output.	No
Vessel profile: Area, maximum diameter, minimum diameter measured from selected vessel cross section	Yes, Similar Vessel Profile: maximum and minimum diameter measures from selected vessel cross sections	Yes	Yes, Similar

Predicate Device Comparison			
Topic	Proposed Device	Primary Predicate Device	Secondary Predicate Device
Manufacturer	Artrya Ltd.	Caristo	Artrya Ltd.
Model Name	Salix Coronary Plaque (V1.0.0)	CaRI-Plaque	Salix Central
510(k) Number	Subject Device: K251837	K242240	K243038
Lumen profile: Area, maximum diameter, minimum diameter measured from selected lumen cross section	Yes, Similar Lumen Profile: maximum and minimum diameter measures from selected vessel cross sections	Yes	Yes, Similar
Vessel, plaque, and lumen segmentation	Yes. Semi-automatic with full option to manually edit with output demonstrated to meet pre-determined acceptance criteria in clinical performance study.	Yes. Semi-automatic (threshold-based segmentation with full option to edit); output demonstrated to meet pre-determined acceptance criteria in clinical performance study.	Deep learning based, vessel & lumen only; validated with ground truth by clinician expert readers, with full option to edit.

Human Factors Engineering (HFE) Testing

HFE formative testing was conducted to verify usability and to identify previously unknown use-related hazards and use errors, as well as provide any additional critical knowledge needed for the safe and effective use of Salix Coronary Plaque in accordance with its intended use and performance claims.

Performance Testing

Performance testing was conducted to verify compliance with specified design requirements in accordance with FDA 21 CFR Part 820.30, IMDRF/SaMD WG/N12FINAL:2014, ISO 13485:2016, IEC 62304:2015, ISO 14971:2019 and NEMA 3.1-3.20 (2016) DICOM standards.

Verification and validation testing were conducted to ensure specifications and performance of the device and were performed per 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”.

Salix Coronary Plaque has been tested according to the specifications that are documented in a master Software Verification and Validation Plan. Clinical Performance and Functional Performance testing are an integral part of Artrya’s software product development process as described in the company’s Quality Management System Policies and Procedures.

Clinical Validation Studies:

A retrospective, multi-reader multi-case design was used to compare SCP-generated plaque volumes and CAD-RADS™ stenosis grades with an expert ground-truth. The final dataset comprised cases from 103 adult patients (58 women, 45 men; mean 61 ± 12 years, range 23–84) imaged at seven geographically diverse U.S. centers (Wisconsin, New York, Arizona and Alabama).

Self-reported race was 57 % White, 22 % Black or African American, 12 % Asian and 2 % American Indian/Alaska Native; 7 % declined/unknown. 13% identified as Hispanic or Latino. Scans were acquired on contemporary 64-detector row or newer systems from Canon, GE, Philips and Siemens, ensuring vendor diversity.

Independent Level III-qualified (or equivalent experience) experts produced vessel-wall and lumen segmentations and assigned CAD-RADS stenosis categories that served as the reference standard. Discrepancies between the expert readers was resolved by a third independent adjudicator with Level III qualifications or equivalent experience. SCP-derived ground truth metrics included total, calcified, non-calcified and low-attenuation plaque volumes.

Eight U.S.-licensed radiologists and cardiologists—each with 2 to 8 years of independent CCTA practice—acted as SCP readers, reflecting routine clinical users in a standard of care setting rather than expert core-lab analysts.

Before study initiation, readers completed one structured training session based on the device Instructions for Use and reviewed at least three sample cases. During the evaluation, each case was interpreted by three distinct SCP readers. They began with the device’s standalone automated output and made any refinements they deemed necessary; no pre-editing by technicians or a core laboratory was allowed.

Additionally, performance validation testing was performed for the ML-enabled Salix Coronary Plaque outputs for calcium scoring, centerline extraction, vessel labelling, and lumen and vessel wall segmentation against reference ground truth established by board certified cardiologists and radiologists with SCCT Level III certification (or equivalent experience) using manual annotation and segmentation tools. In each case the reference was independently established from the source clinical image interpretation.

Data for the validation was sourced from multiple unique centers in the USA that did not contribute any data to the training datasets for any Salix Central algorithm.

The validation dataset consisted of de-identified cardiac CT studies from seven (7) centers across four (4) US states. This consisted of 302 non-contrast series for the testing of calcium scoring, 107 contrast-enhanced series for the testing of centerline extraction, vessel labelling, and wall segmentation. Each validation test included representation of multiple scanner manufacturers (i.e., Canon, GE, Philips, and Siemens) and disease severity based on calcium score and maximum stenosis (CAD-RADS classification) based on the source clinical radiology reports.

Salix Coronary Plaque performance exceeded all the pre-defined acceptance criteria for all validation tests.

Salix Coronary Plaque Output	Statistic	Estimate [95% CI]	Acceptance Criteria	Result
Vessel Level Stenosis	Percentage within one CAD-RADS category	95.8% [94.1%, 97.3%]	90%	Pass
Total plaque	ICC3 ¹	0.96 [0.94, 0.98]	0.70	Pass
Calcified plaque	ICC3 ¹	0.96 [0.90, 0.99]	0.80	Pass
Noncalcified plaque	ICC3 ¹	0.91 [0.84, 0.95]	0.55	Pass
Low attenuating plaque	ICC3 ¹	0.61 [0.41, 0.93]	0.30	Pass
Calcium Scoring	Pearson Correlation	0.958 [0.947, 0.966]	0.90	Pass
Centerline Extraction	Overlap score	0.8604 [0.8445, 0.8750]	0.80	Pass
Vessel Labelling	F1 Score	0.8264 [0.8047, 0.8479]	0.70	Pass
Lumen Wall Segmentation	Dice Score	0.8996 [0.8938, 0.9055]	0.80	Pass
Vessel Wall Segmentation	Dice Score	0.9016 [0.8962, 0.9070]	0.80	Pass

¹Intraclass correlation coefficient two-way mixed model ICC(3, 1) was used.

This data supports our claim that qualified clinicians with minimal SCP specific training can achieve SCCT expert-level performance with SCP without the support of a core laboratory or specialized technician pre-read.

Conclusion

The comprehensive performance testing and comparison to primary and secondary predicates CaRi-Plaque (K242240) and Salix Central (K243038), respectively, supports that Salix Coronary Plaque (K251837) is substantially equivalent to the named predicate devices. The device has the same intended use as the predicate devices and minor differences in expanded indications compared to the predicates that do not affect its safety and effectiveness. Minor differences in technological characteristics between the devices do not raise unique questions of safety or effectiveness, which have been addressed in accordance with Artrya's Quality Management System.