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

March 27, 2025

Re: K243038
Trade/Device Name: Salix Central
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: February 27, 2025
Received: February 27, 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243038

Device Name

Salix Central

Indications for Use *(Describe)*

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.

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.

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-automated features are intended for an adult population and should only be used by qualified medical professionals experienced in examining cardiac CT images.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K243038

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:	February 25, 2025
Submitter:	Artrya Ltd.
Official Contact:	Gabriela Quijada 1257 Hay Street West Perth, 6005, Australia Phone: +61 405 653 605
Proprietary Name:	Salix Central
Common Name:	System, Image Processing, Radiological
Classification:	Class II Medical Device Regulation Number: 21 CFR 892.2050 Product Code: QIH
Predicate Device:	cvi42 Auto Imaging Software Application (K213998)
Reason For Submission:	New Traditional 510(k)

Indications for Use

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.

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.

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-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.

Device Description

Salix Central is a web-based software application, hosted on AWS cloud 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 calcified plaque (calcium scoring). 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.

A reference standard was created to train the machine learning (ML) enabled algorithms in Salix Central. Data for training and validation sampled from our database based on pre-defined exclusion criteria. Data were also selected to ensure no site was shared by training and validation cohorts. The training dataset included 3835 unique patient cases from 6 unique sites from the USA, Canada, Australia and Japan.

Substantial Equivalence Discussion

Salix Central is substantially equivalent to the predicate, cvi42 Auto Imaging Software Application (K213998). Both devices and the reference device, iNtuition-Structural Heart Module (K191585), have the same Intended Use/Indications for Use and are similar with respect to key features and performance characteristics. The Predicate Device & Reference Device Comparison Table below provides a comparison between the Salix Central and the predicate device cvi42 Auto Imaging Software Application (K213998) and reference device, iNtuition-Structural Heart Module (K191585):

Predicate Device & Reference Device Comparison			
Topic	**Proposed Device**	**Predicate Device**	**Reference Device**
Manufacturer	Artrya Ltd.	Circle Cardiovascular Imaging Inc.	TeraRecon, Inc.
Model Name	Salix Central	cvi42 Auto Imaging Software Application	iNtuition-Structural Heart Module
510(k) Number	Subject Device: K243038	K213998	K191585

Predicate Device & Reference Device Comparison			
Topic	**Proposed Device**	**Predicate Device**	**Reference Device**
Manufacturer	Artrya Ltd.	Circle Cardiovascular Imaging Inc.	TeraRecon, Inc.
Model Name	Salix Central	cvi42 Auto Imaging Software Application	iNtuition-Structural Heart Module
510(k) Number	Subject Device: K243038	K213998	K191585
Intended Use / Indications for Use	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. 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.	cvi42 Auto is intended to be used for viewing, post-processing, qualitative and quantitative evaluation of cardiovascular magnetic resonance (MR) and computed tomography (CT) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables a set of tools to assist physicians in qualitative assessment of cardiac images and quantitative measurements of the heart and adjacent vessels; perform calcium scoring; and to confirm the presence or absence of physician-identified lesion in blood vessels.	iNtuition-Structural Heart Module is a software solution that is intended to assist Cardiologists, Radiologists and Clinical Specialists with the visualization and measurements of structures of the heart and vessels. iNtuition-Structural Heart Module enables the user to: - Visualize and measure (diameters, lengths, angles, areas and volumes) structures of the heart and vessels for pre-operative planning and sizing for cardiovascular interventions and surgery, and for post- operative evaluation. - Quantify calcium (volume, density) - iNtuition-Structural Heart Module has the following

Predicate Device & Reference Device Comparison			
Topic	**Proposed Device**	**Predicate Device**	**Reference Device**
Manufacturer	Artrya Ltd.	Circle Cardiovascular Imaging Inc.	TeraRecon, Inc.
Model Name	Salix Central	cvi42 Auto Imaging Software Application	iNtuition-Structural Heart Module
510(k) Number	Subject Device: TBD	K213998	K191585
	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-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.	The target population for cvi42 Auto's manual workflows is not restricted; however, Salix Central's semi-automated machine learning algorithms are intended for an adult population. cvi42 Auto shall be used only for cardiac images acquired from an MR or CT scanner. It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR or CT images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process.	tools and features that facilitate: - Automatic and manual centerline detection. - Segmentation of cardiovascular structures
Device Class	II	II	II
Device Classification	QIH	LLZ, QIH	LLZ
Intended Users	Cardiologists, Radiologists and Clinical Specialists	Qualified Medical Professionals	Cardiologists, Radiologists and Clinical Specialists
Operating Platform	Client-Server Google Chrome Application	macOS, Microsoft Windows	Microsoft Windows
DICOM Compliant	Yes; DICOM 3.0 or higher	Yes	Yes
Image Acquisition	CT	MR and CT	CT, MR, Nuc, PET, Angio, US/Echo, SPECT
Secured Network Server Integration	Yes	Yes	Yes
Store Images	Yes	Yes	Yes
2D Imaging	Yes	Yes	Yes
3D Imaging	Yes	Yes	Yes
Multiplanar Reformat (MPR)	Yes	Yes	Yes
Study Analysis – Navigation Tools	Panning Windowing Zooming	Panning Windowing Zooming	Yes

Predicate Device & Reference Device Comparison			
Topic	**Proposed Device**	**Predicate Device**	**Reference Device**
Manufacturer	Artrya Ltd.	Circle Cardiovascular Imaging Inc.	TeraRecon, Inc.
Model Name	Salix Central	cvi42 Auto Imaging Software Application	iNtuition-Structural Heart Module
510(k) Number	Subject Device: TBD	K213998	K191585
	Series, slices, and phases	Series, slices, and phases	
Study Analysis – Visualization and Editing	Centerline Wall Signal Intensity Overlay	Yes	Yes
Measurements	Distance Diameter Area Hounsfield Unit (HU) Lumen % diameter reduction	Distance Perimeter Area Hounsfield Unit (HU) Volume	Yes
Centerline Extraction and Wall Segmentation	Manual and semi-automatic / user-editable	Manual and semi-automatic using Machine Learning technique	Semi-automatic
Calcium Scoring	Yes	Yes	Yes
Reporting	Yes	Yes	Yes

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

Performance Validation Testing:

Performance validation testing was performed for the ML-enabled Salix Central 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 3 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 363 unique, de-identified cardiac CT studies from six (6) centers across three (3) US states. This consisted of 302 non-contrast series for the testing of calcium scoring, 116 contrast-enhanced series for the testing of centerline extraction and vessel labelling, and 63

contrast-enhanced series for the testing of 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.

The combined dataset consisted of:

- 36% age 65 and above (median age 60)
- 57% Female
- 67% White, 18% Black or African American, and 13% Asian
- 19% Hispanic or Latino

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

Salix Central Output	Statistic	Estimate [95% CI]	Acceptance Criteria	Result
Calcium Scoring	Pearson Correlation	0.958 [0.947, 0.966]	0.90	Pass
Centerline Extraction	True Placement Percentage	90.4% [88.5%, 92.2%]	78%	Pass
Vessel Labelling	F1 Score	78.4% [96.1%, 80.5%]	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

Conclusion

In summary, the comprehensive performance testing and comparison to the predicate cvi42 Auto Imaging Software Application (K213998) demonstrates that Salix Central is substantially equivalent to the named predicate device.