



April 16, 2025

LARALAB GmbH
% John Smith
Partner
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, District of Columbia 20004

Re: K242500
Trade/Device Name: LARALAB
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 22, 2025
Received: March 24, 2025

Dear John Smith:

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, appearing to read "Samuel R. Lamb", is written over a large, light blue, semi-transparent "FDA" watermark. The signature is fluid and cursive. To the right of the signature, the word "for" is printed in a standard black font.

Jessica Lamb, PhD
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K242500

Device Name

LARALAB

Indications for Use (Describe)

LARALAB enables visualization, assessment and measurement of cardiovascular structures for:

- Preprocedural planning and sizing for cardiovascular interventions and surgery
- Postprocedural image review

To facilitate the above, LARALAB provides general functionality such as:

- Automatic segmentation of cardiovascular structures and other objects of interest (calcifications)
- Automatic measurements
- Manual measurement and adjustment tools
- Visualization and image reconstruction techniques: Multiplanar Reconstruction (MPR), Surface rendering
- Reporting tools

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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510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter

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Preparation Date	March 19, 2025
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Device Information

Trade Name:	LARALAB
Common Name:	LARALAB
Classification:	Medical image management and processing system
Regulation Number:	21 CFR § 892.2050
Product Code:	QIH
Device Class:	Class II
510(k) Number:	K242500

Predicate Device

Device Name:	3mensio Workstation
510(k) Number:	K153736
Manufacturer:	Pie Medical Imaging B.V.

Device Description

LARALAB is a stand-alone software developed to enable cardiologists, radiologists, heart surgeons and healthcare professionals (“Users”) to import, view and process Medical Images. In particular, the software generates pre-calculated automatic segmentations and measurements based on deterministic Deep Learning Algorithms. Based on the output of the Deep Learning Algorithms, the User is able to further visualize, assess and measure (“Case Planning”) various anatomical structures of the heart in the context of cardiovascular procedures (e.g., TAVR) such as heart valves, heart chambers, cardiac tissue and vessels, as well as such vessels and tissue relevant as access routes.

Intended Use

LARALAB is a software application that is intended to provide cardiologists, radiologists, heart surgeons and healthcare professionals additional information to aid them in reading and interpreting DICOM compliant medical images of structures of the heart and vessels. LARALAB enables the user to make:

Visualizations, assessments and measurements (e.g. splines, distances, angulation, volumes) of structures of the heart and vessels, including such vascular structures relevant as access routes in the context of cardiovascular procedures.

Indications for Use

LARALAB enables visualization, assessment and measurement of cardiovascular structures for:

- Preprocedural planning and sizing for cardiovascular interventions and surgery
- Postprocedural image review

To facilitate the above, LARALAB provides general functionality such as:

- Automatic segmentation of cardiovascular structures and other objects of interest (calcifications)
- Automatic measurements
- Manual measurement and adjustment tools
- Visualization and image reconstruction techniques: Multiplanar Reconstruction (MPR), Surface rendering
- Reporting tools

Technological Characteristics Comparison

LARALAB is substantially equivalent to the predicate device, 3mensio Workstation (K153736). Both devices share the same general intended use and similar indications for use, focusing on the visualization and measurement of cardiovascular structures. While LARALAB introduces new features, such as cloud-based access and automatic preprocessing through deep learning algorithms, these differences do not raise new questions of safety or effectiveness. Both devices enable automatic image segmentation for which the output is user reviewed and adapted if needed. The predicate device offers additional functionality for assessing coronary arteries.

	Subject Device	Predicate Device	Comparison
Device	LARALAB	3mensio Workstation	/
Product Code	QIH	LLZ	Similar, the subject device implements artificial intelligence including nonadaptive

			machine learning algorithms.
Classification	Medical image management and processing system	Medical image management and processing system	Same.
Regulation Number	21 CFR § 892.2050	21 CFR § 892.2050	Same.
Intended Use	LARALAB is a software application that is intended to provide cardiologists, radiologists, heart surgeons and healthcare professionals additional information to aid them in reading and interpreting DICOM compliant medical images of structures of the heart and vessels. LARALAB enables the user to make: - Visualizations, assessments and measurements (e.g., diameters, lengths, areas, volumes, angles) of structures of the heart and vessels, including such vascular structures relevant as access routes in the context of cardiovascular procedures.	3mensio Workstation is a software solution that is intended to provide cardiologists, radiologists and clinical specialists additional information to aid them in reading and interpreting DICOM compliant medical images of structures of the heart and vessels. 3mensio Structural Heart enables the user to: - Visualize and measure (diameters, lengths, areas, volumes, angles) structures of the heart and vessels - Quantify calcium (volume, density) 3mensio Vascular enables the user to: - Visualize and assess stenosis, aneurysms and vascular structures - Measure the dimensions of vessels (diameters, lengths, areas, volumes, angles)	While minor textual differences exist, the intended uses of the two devices are otherwise the same.
Indications for Use	The LARALAB software enables visualization, assessment and measurement of cardiovascular structures for: - Preprocedural planning and sizing for cardiovascular interventions and surgery - Postprocedural image review To facilitate the above, LARALAB provides general functionality such as: - Automatic segmentation of cardiovascular structures and other objects of interest (calcifications) - Automatic measurements - Manual measurement and adjustment tools - Visualization and image	3mensio Workstation enables visualization and measurement of structures of the heart and vessels for: - Pre-operational planning and sizing for cardiovascular interventions and surgery - Postoperative evaluation - Support of clinical diagnosis by quantifying dimensions in coronary arteries - Support of clinical diagnosis by quantifying calcified plaques (calcium scoring) in the coronary arteries To facilitate the above, the 3mensio Workstation provides general functionality such as: - Segmentation of cardiovascular structures - Automatic and manual centerline detection - Visualization and image reconstruction techniques: 2D review, Volume Rendering, MPR,	Substantially the same. Both devices are indicated for use in preprocedural planning and postprocedural assessment of structural heart interventions. The predicate device also supports clinical diagnosis by quantifying calcifications and quantifying dimensions in coronary arteries. In order to provide these functions, the predicate device supports a wider range of viewing functionality (e.g., volume rendering and other general visualization and image reconstruction techniques) than the subject device. The additional quantifying function for the evaluation of calcifications and coronary artery dimensions and additional general visualization and image reconstruction techniques are not

	reconstruction techniques: Multiplanar Reconstruction (MPR), Surface rendering, 4D views - Reporting tools	Curved MPR, Stretched CMRP, Slabbing, MWP, ALP, MiniP - Measurement and annotation tools - Reporting tools	necessary for the subject device to perform as intended and not including those functions does not impact the performance of the subject device or the ability to use the subject device as intended.
Software Access	Cloud based. The LARALAB software includes cloud-based and related cybersecurity functionality for cloud-based devices, including: - User authentication - Data encryption (HTTPS/SSL) in transit and at rest - Encrypted data storage - Third party cloud services compliant with security standards	Traditional client install. 3mensio is a traditional software package, to be installed on a specific computer.	Although the subject device is cloud-based and the predicate device is a traditional software package that needs to be installed on a specific computer, this difference in application access does not impact the intended use or the performance of the device, which remain substantially equivalent. Any risks related to accessing the application in the cloud that do not exist for a specific computer installation are fully mitigated by the cybersecurity functionality of the subject device. Therefore, these minor differences do not raise different questions of safety or effectiveness.
Import of patient data	- Upload from local device	- Import from local device - Import from PACS	Both devices offer similar import/upload functions. The limited difference is due to the cloud-based nature of the subject device, which requires that patient data be uploaded, as opposed to directly importing data from a PACS system, into the local predicate device.
DICOM Support	- CT data in DICOM format (vendor independent) - Upload DICOM files	- CT data in DICOM format (vendor independent) - Import DICOM files - DICOM compliance for CT, Ultrasound images	Similar. Predicate device offer additional functionality for ultrasound images.
Data privacy	- Data de-identification before upload (Protected Health Information (PHI) can completely be removed and does not leave the client or hospital)	- Data de-identification	Data privacy is effectively the same between the subject and predicate devices. For both devices patient data is de-identified and no protected health information leaves the facility (either because it is removed before the data is uploaded, as in the subject device, or because

			the data remains on site, as in the predicate device).
Data management functionality	- Study list overview - Deleting - Search - Sorting - Export	- Study list overview - Deleting - Search - Sorting - Export	Same.
Automatic analyses	Automatic processing generating: - Volumetric segmentations of cardiovascular structures based on deterministic Deep Learning algorithms - Measurements (e.g. splines, distances, angulation, volumes) - Assessments containing Automatic Pre-calculated views	Automatic segmentation toolset: - Automatic segmentations - Automatic centerline	Both devices include automated segmentation functionality and both devices include the option for the physician to review the segmentation. There are slight differences between the underlying automatic analysis concepts between the devices. Specifically, the subject device provides the user with pre-calculated segmentations/measurements/assessments, which the user can review/adjust/approve. Alternatively, the predicate device includes automated and manual steps. However, in both cases, the type of information outputted by the device is identical.
Image Assessment Tools	- Length measurement - Spline/diameter measurement - Angle Measurement - Volume measurements - Zoom / Pan / Rotation / Windowing tools - Markers / Annotation tool - C-arm angulation calculation	- Length measurement - Spline/diameter measurement - Angle measurement - Volume measurements - Zoom / Pan / Rotation / Windowing tools - Markers / Annotation tool - C-Arm angulation calculation Additional tools for vascular assessment: - Calcium scoring for assessment of calcium in the aortic root - Calcium scoring for assessment of calcium in the coronary arteries - Segmentation and analysis of coronary artery tree centerline	Similar. Predicate device offers additional functionality for coronary artery assessment.
Visualizations	2D - Multiplanar Reconstruction (MPR) - Coloured overlays (of segmented objects)	2D - Multiplanar Reconstruction (MPR) - Maximum intensity projection (MIP)	Similar. Predicate device offers additional functionality for image assessment.

	3D - Surface rendering	- Minimum-intensity projection (MinIP) - AvelP - Curved (CPR) cross-curved, stretched Planar Reformation 3D - MIP volume rendering - Color volume rendering - Grayscale volume rendering	
Storage and Export of Results	- Session state - Report in PDF format	- Session state - Report in PDF format	Same.
System Outputs	- Case Planning results, incl.: - Measurements - Screenshots - Assessments	- Case Planning results, incl.: - Measurements - Screenshots - Assessments	Same.

The subject and the predicate device have the same intended use and similar indications, technological characteristics and principles of operation, there are only limited technological differences. These differences do not alter the intended use of the application nor do they raise different questions of safety or effectiveness. Both the subject and predicate device generate the same type of measurements and have been directly compared against one another to demonstrate comparable performance (see performance data). The provided detailed comparison demonstrates the subject device is substantially equivalent to the predicate device.

Performance Data

Comprehensive performance testing was conducted, including the evaluation of automatic pre-calculated segmentations and measurements against reference ground-truth values obtained by expert clinicians with the predicate device. The results showed high accuracy and agreement with the predicate device, meeting all predefined acceptance criteria. The performance tests included statistical methods such as Bland-Altman analysis and intraclass correlation coefficient (ICC) calculations, confirming the reliability and consistency of LARALAB's measurements.

Cohort Characteristics

The performance testing was based on a multi-centric observational cohort study involving a total of 60 patient datasets. The cohort was evenly divided among patients indicated for aortic, mitral, and tricuspid valve interventions, with each comprising 33.3% of the cohort. The age range of the studied cohort was 62-97 years, with 45% male subjects. The cohort included CT scans from different CT manufacturers and covered imaging parameters such as different slice thickness and contrast enhancement. No datasets were included that were used for training the deep learning models.

Testing Methodology

The accuracy of automatic pre-calculated segmentations was evaluated using Dice score, Mean Surface Distance (MSD), and 95th percentile Hausdorff distance (95% HD) metrics. The segmentations covered various cardiovascular structures, including the left atrium (LA), left ventricle (LV), right atrium (RA), right ventricle (RV) and others. The accuracy of automatic pre-calculated measurements was assessed using Bland-Altman analysis, which evaluated the mean bias and 95% limits of agreement between LARALAB's measurements and the ground-truth measurements. The intraclass correlation coefficient (ICC) was also calculated to assess the consistency between the manual measurements (ground truth) generated with the predicate device by the clinical experts.

Results

Segmentations: The Dice score analysis demonstrated that LARALAB achieved high accuracy in segmenting primary cardiovascular structures, with Dice scores ranging from 0.89 to 0.98 for major structures such as the LA, LV, RV, and RA. Secondary and tertiary structures also met the predefined acceptance criteria.

Measurements: Bland-Altman analysis showed that the agreement between LARALAB's automatic pre-calculated measurements and ground-truth measurements was within the predefined acceptance criteria for all assessed parameters. The ICC values were above 0.75 for all measurements, indicating excellent agreement between the clinical experts' manual measurements. The study concluded that LARALAB's automatic pre-calculated segmentations and measurements are as accurate and reliable as those obtained using the predicate device. Overall, comparable performance was achieved on all variability factors including geographic location, scanners, slice thickness, age, and gender.

Limitations: This device has only been tested on patients aged 62 years and older.

Cybersecurity Testing

An external cybersecurity assessment, including penetration testing, was successfully completed to evaluate the system's security posture. No medium or high-risk vulnerabilities were identified, and a strong overall security posture with no critical issues was confirmed. The testing was conducted in accordance with the FDA guidance document *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*.

Conclusion

The performance data and substantial equivalence comparison demonstrate that LARALAB is as safe and effective as the predicate device for its intended use. Therefore, LARALAB is substantially equivalent to the predicate device, raising no new questions of safety or effectiveness.