February 6, 2026

Augmented Reality Software S.L.
% Juan Tezak
Consultant
Compliance 4 Devices
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K251577
Trade/Device Name: LAIA XR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 15, 2026
Received: January 15, 2026

Dear Juan Tezak:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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
DHT8B: Division of Radiological 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251577

Please provide the device trade name(s).

LAIA XR

Please provide your Indications for Use below.

LAIA XR is a software device for displaying digital medical images, especially for CT and MR images (DICOM format). It is intended to visualize 3D medical imaging of the patient for pre-operative planning outside the surgical room.

When accessing LAIA XR from a wired head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. LAIA XR is indicated for use by qualified healthcare professionals including surgeons, radiologists, physicians, and technologists.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
LAIA XR

K251577

Prepared February 04, 2026

I) Applicant

Submitter	Augmented Reality Software S.L.
Address	Calle del Adaja 10. Villamayor 37185. Salamanca, Spain.
Contact	Mr. Santiago González Izard
Telephone	+34 644 236 306
E-mail	santiago.gi@arsoft-company.com

II) Device

Trade Name	LAIA XR
Common Name	Picture Archiving and Communications System
Classification Name	Medical image management and processing system
Regulation Number	892.2050
Product Code	LLZ

III) Predicate Device

510(k) Number	K213215
Applicant	apoQlar GmbH
Trade Name	VSI HoloMedicine®
Classification Name	Medical image management and processing system
Regulation Number	892.2050

IV) Indication For Use

LAIA XR is a software device for displaying digital medical images, especially for CT and MR images (DICOM format). It is intended to visualize 3D medical imaging of the patient for pre-operative planning outside the surgical room.

When accessing LAIA XR from a wired head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. LAIA XR is indicated for use by qualified healthcare professionals including surgeons, radiologists, physicians, and technologists.

V) Device Description

LAIA XR is a software device for displaying digital medical images, especially for CT and MR images (DICOM format). It is intended to visualize 3D medical imaging of the patient for pre-operative planning outside the surgical room.

When accessing LAIA XR from a wired head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. LAIA XR is indicated for use by qualified healthcare professionals including surgeons, radiologists, physicians, and technologists.

The device consists of a software-based medical system, which runs on a standard computing platform (e.g., a laptop or desktop computer) with a display screen. Optionally, the system can be used in conjunction with virtual reality (VR) goggles to provide an immersive three-dimensional (3D) visualization environment; however, the use of VR hardware is not required for the software to perform its intended functions.

LAIA XR provides interactive visualization capabilities for three-dimensional medical images and includes functionalities and tools that support pre-operative planning activities, including the following:

- Advanced 3D visualization of anatomical structures,
- 2D and 3D multi-planar reconstruction views, with customizable transfer functions (color and opacity mappings) to highlight specific tissues or structures,
- Quantitative measurement tools, such as distance and angle measurements,
- Fiducial marker placement within defined regions of interest (ROIs),
- Capture and screenshots of 3D models for use in surgical preparation,
- Step-by-step surgical planning documentation, including written notes and screenshot capture.

These functionalities allow healthcare professionals to interact with and organize medical imaging data as part of pre-operative planning workflows.

The aim of the medical device software (MDSW) is to support healthcare personnel in the review and manipulation of CT and MR images. LAIA XR provides an interactive platform that allows users to view, manipulate, and organize medical image data for pre-operative planning purposes.

VI) Comparison of Technological Characteristics

The review of the indications for use and comparison characteristics provided in the table below demonstrate that LAIA XR is substantially equivalent to the predicate device.

Item #	Device Characteristic	Subject Device LAIA XR	Predicate Device VSI HoloMedicine®	Comparison
1	510 (k) Number	K251577	K213215	-
2	Device Name, Model	LAIA XR	VSI HoloMedicine®	-
3	Manufacturer	Augmented Reality Software S.L.	apoQlar GmbH	-
4	CFR Reference	21 CFR 892.2050	21 CFR 892.2050	Same
5	FDA Review Panel	Radiology	Radiology	Same
6	FDA Device Name	System, Image Processing, Radiological	System, Image Processing, Radiological	Same
7	FDA Product Code	LLZ	LLZ	Same
8	Class	II	II	Same
9	Indications for use	LAIA XR is a software device for displaying digital medical images, especially for CT and MR images (DICOM format). It is intended to visualize 3D medical imaging of the patient for pre-	VSI HoloMedicine is a software device for displaying digital medical images acquired from CT, Angio CT, MRI, CBCT, PET, and SPECT sources. It is intended to visualize 3D imaging holograms of the patient for	Similar

Item #	Device Characteristic	Subject Device LAIA XR	Predicate Device VSI HoloMedicine®	Comparison
		operative planning outside the surgical room. When accessing LAIA XR from a wired head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. LAIA XR is indicated for use by qualified healthcare professionals including surgeons, radiologists, physicians, and technologists.	pre-operative planning outside and/or inside the surgical room. When accessing VSI HoloMedicine from a wireless head-mounted display (HMD) or PC monitor, images viewed are for informational purposes only and not intended for diagnostic use. VSI HoloMedicine is indicated for use by qualified healthcare professionals including surgeons, radiologists, physicians, and technologists.	
10	Intended Use Environment	The software is intended to be used: • In office environments within hospitals or at any other location with a computer • For informational only purposes at any location using the head-mounted display (HMD)	The software is intended to be used: • In operating rooms • In office environments within hospitals or at any other location with a computer • For informational only purposes at any location using the head-mounted display (HMD)	Similar
11	Intended Users	Healthcare personnel who regularly use medical images for diagnosis in their workflow. Especially for surgeons who perform surgical planning.	Qualified healthcare professionals including surgeons, radiologists, physicians.	Similar
12	Patient Population	It does not have a limitation of patients; the only requirement is to have radiological images.	The device is a software which allows for viewing of DICOM data. Therefore, its intended use is without any restrictions regarding patient population.	Similar
13	Prescription or OTC	Prescription	Prescription	Same
14	Main System components	LAIA XR Viewer: includes the surgical planning modules, visualization tools and patient manager. LAIA XR Image Processing: generates the image in 3D. LAIA XR Patient Database: module with patient information. LAIA XR is a healthcare software which does not depend on any hardware to be used. However, to use the virtual reality version, a device compatible with the Meta Quest environment is required.	VSI HoloMedicine® software, and Headset (Microsoft HoloLens 2)	Similar
15	Spatial Mapping	Spatial mapping provides a representation of real-world surfaces around the device	Spatial mapping provides a representation of real-world surfaces around the device	Same
16	Imaging Modality	CT and MR	CT, Angio CT, MRI, CBCT, PET CT and SPECT CT	Similar
17	Data Type Supported	• DICOM	• DICOM • OBJ • STL • JPEG	Similar

Item #	Device Characteristic	Subject Device LAIA XR	Predicate Device VSI HoloMedicine®	Comparison
			• PNG • MP4 • PDF	
18	Image View/Manipulation	• Level • Reset • Image Rotate • Manually arrangingobject dimensions	• Level • Reset • Image Rotate • Manually arrangingobject dimensions	Same
19	Communication between Headset and computer	Wireless linking system or by using a cable	Wireless, encrypted	Similar
20	Data Encryption	• HTTPS • SSL	• HTTPS • SSL	Same
21	Patient Demographic Display	The system has no sensitive information other than what is already present in the hospital's own patient data system, from which it requests the information.	Only the external ID that is provided to the patient after signing the patient agreement is displayed	Similar
22	User and Password Control	Users have own credential information to access. Users can be managed via an internal database and active directory	Users have own credential information to access. Users can be managed via an internal database and active directory	Same
23	Data Security	Stored on server	Stored on server	Same
24	MPR Viewing	This viewing feature enables the display of CT and MRI images (in DICOM format) into axial, coronal and sagittal orientations independently of their original orientation.	This viewing feature enables the display of CT, MRI, CBCT, Angio CT, PET CT and SPECT CT images into axial, coronal and sagittal orientations	Same
25	3D Volume Rendered Viewing	This viewing feature enables the display of 3D perspective views of CT or MRI, images set that have been transformed into volumes. For this purpose, clinically validated three-dimensional visualization technology is used: Marchant rays. It also provides presets to enable users to alter the visualization parameters of the 3D views to highlight features. It also provides preset creation.	This viewing feature enables the display of 3D perspective views of CT, MRI, CBCT, angio CT, PET CT and SPECT CT images sets that have been transformed into volumes. It also provides presets to enable users to alter the visualization parameters of the 3D views to highlight features	Similar
26	Diagnostic Quality Medical image review	Ability to provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices	Ability to provide diagnostic quality medical image review for multi-dimensional digital images acquired from a variety of imaging devices	Same
27	Surgical planning	Saving and loading configurations and arrangements of medical images, marks, measurements and 3D models on the mixed platform PC-VR. Ability to create a sequence of steps for later consultation during the planning phases.	Saving and loading configurations of medical images, marks, and 3D models on HMD Ability to save and load combinations and arrangement of objects displayed in the 3D space on HoloLens for planning purposes. In case it is used during surgical interventions, must not replace the role of traditional medical imaging screens.	Similar
28	Creating documentation	Ability to create and view resources on the PC-VR mixed platform, including	Ability to create and view documentation on the HoloLens device, including	Similar

Item #	Device Characteristic	Subject Device LAIA XR	Predicate Device VSI HoloMedicine®	Comparison
		pictures, videos, specific 3D models configurations and audio recordings.	pictures, videos and speech to text notes.	
29	View of 2D pictures	Ability to view 2D pictures on the mixed platform PC-VR. Interact with it by dragging, scaling and rotation.	Ability to view 2D pictures on HoloLens. Interact with it by dragging, scaling and rotation.	Same
30	Help tips	Ability to display tooltips for the different functionalities of the platform. These tooltips explain what the "button" or the "menu" does to the user.	It has not a feature to educate users on certain functionality that may not be obvious to a new user	Different
31	Transmission Modes	The information in the application is transmitted through wired network using HTTP protocol with the TLS security layer using SSL encryption in the server-client communication, this is the only way the information is transmitted.	Via web with Internet browsers and wireless. VSI HoloMedicine® contains wireless technology and the wireless information transfer is encrypted with 256 encryption for data security	Different
32	Support for TIF Files	LAIA XR cannot display TIF files.	VSI HoloMedicine® cannot display TIF files.	Same
33	Crosshair Navigation and Synchronization	LAIA XR can, at the same time, visualize different views of the 3d model along with MPR images or resources.	VSI HoloMedicine® has not the feature that provides a facility to synchronize and scroll through multiple views at the same time.	Different
34	HoloNetwork	Meta Quest goggles, but any virtual reality device operating under the OpenXR standard.	The HoloLens part of the system should contains an interactive hologram of the Earth that would display information on locations of the HoloMedicine® Expert Group members along with their title, first name, last name and country of residence.	Different

LAIA XR and its predicate VSI HoloMedicine® are very similar products in terms of their intended use, composition and effectiveness in visualize 3D medical imaging.

ARSOFT determines that each difference between the devices resulted in no impact to the performance, safety or efficacy of LAIA XR when compared to VSI HoloMedicine®.

VII) Technological Characteristics

Target group of patients and intended user	Intended users: Healthcare personnel who regularly use medical images for diagnosis in their workflow. Especially for surgeons who perform surgical planning. Patients: It does not have a limitation of patients; the only requirement is to have radiological images.
Contraindications	In the event that the medical image does not have an acceptable quality, it is recommended not to rely on the three-dimensional reconstruction of the LAIA XR software. The use of a poor-quality medical image can lead to imperfect and inaccurate reconstruction and can lead to misinterpretation.
Warnings and Precautions	WARNING: Only trained and qualified healthcare professionals

shall operate the system. Improper use of the software may result in incorrect clinical decisions. Training must be completed prior to first use. Refer to user manual for training requirements.

WARNING: The uploaded study does not meet the minimum slice thickness requirements. This may affect the quality of the reconstruction.

WARNING: Patient profile creation failed. Please verify that all required information in the application form is complete.

WARNING: The uploaded study does not correspond to the intended imaging modality (CT or MRI).

WARNING: The uploaded study is empty, corrupted, or incompatible with the software. Please upload a different file.

CAUTION: Take breaks from using the HMD in accordance with the manufacturer's instructions. If you experience any of the following symptoms while using the HMD — eye strain, dizziness, headaches or auditory discomfort — continue the study in desktop view. Please refer to the HMD user manual for more information.

CAUTION: Be aware of your surroundings when using the VR environment. Maintain a safe distance. There is a risk of collision with surrounding objects.

ATTENTION: LAIA XR is intended for use exclusively by trained and qualified healthcare professionals.

ATTENTION: ARSOFT only ensures proper software functionality when the minimum technical requirements are met. Refer to section 'Technical specifications' of the user manual for further details.

ATTENTION: AROSFT guarantees the proper performance of the software and ensures compatibility with validated VR goggles. Only the Meta Quest 3 VR Headset model has been validated for use.

ATTENTION: Please verify that the version of the user manual available corresponds to the software version. Otherwise, please contact the manufacturer

ATTENTION: You have been logged out due to inactivity

ATTENTION: To ensure the proper functioning and connectivity of the LAIA XR virtual reality environment, please ensure that you have the latest version of Meta Quest Link available

	ATTENTION: To ensure the proper functioning and connectivity of the LAIA XR application, please ensure that you have one of the Operative System (OS) versions indicated in the IFUs
Reasonably foreseeable misuse	The misuse planned for LAIA XR would focus on usability problems due to insufficient system training. On the other hand, the interaction of virtual reality requires a short process of adaptation to the technology that can be confusing for a new user. An insufficient quality medical image will cause an imperfect reconstruction of the three-dimensional medical model that will greatly limit the capabilities of the software and the performance of surgical planning.
Residual risks and side effects	LAIA XR does not generate any significant residual risk or cause side effects on the patient.
Working principle	The software takes advantage of the immersive visualization power offered by new virtual reality technologies and combines it with a wide variety of powerful tools that facilitate the surgical planning process on the three-dimensional image.

VIII) Performance Data

The software LAIA XR has been tested to verify its safety and effectiveness. Both preclinical and clinical tests have been conducted, to determine the device's performance, functionality and reliability characteristics.

Preclinical testing, including design verification and validation testing, software verification, performance testing (accuracy and repeatability), human factors/usability testing and head-mounted display (HMD) bench testing, has been successfully carried out. The device passed all of the tests based on pre-determined pass/fail criteria.

A clinical state-of-the-art evaluation, including a scientific literature assessment, has also been conducted.

As a result of the testing, potential risks were analyzed and satisfactorily mitigated in the device design.

The conclusions drawn from the nonclinical and clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.

IX) Conclusion

The subject device is substantially equivalent in the areas of technical characteristics, general function, application and indications of use to the predicate device K213215.