Galgo Medical S.L
℅ Antoni Riu
General Manager
C/Comte d'Urgell, 143, 4B
Barcelona, Barcelona 08036
SPAIN

January 15, 2020

Re: K191125
Trade/Device Name: ADAS 3D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 1, 2019
Received: December 12, 2019

Dear Antoni Riu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. 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 located 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.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191125

Device Name
ADAS 3D

Indications for Use *(Describe)*

ADAS 3D is indicated for use in clinical settings to support the visualization and analysis of MR and CT images of the heart for use on individual patients with cardiovascular disease.

ADAS 3D is indicated for patients with myocardial scar produced by ischemic or non-ischemic heart disease.
ADAS 3D processes MR and CT images. The quality and the resolution of the medical images determines the accuracy of the data produced by ADAS 3D.

ADAS 3D is indicated to be used only by qualified medical professionals for the visualization and analysis of cardiac images. The data produced by ADAS 3D must not be used as an irrefutable basis or a source of medical advice for clinical diagnosis or patient treatment. The data produced by ADAS 3D is intended to be used to support qualified medical professionals for clinical decision making.

ADAS 3D is not intended to identify regions for catheter ablation or treatment of arrhythmias.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 – 510(k) Summary

K191125

SUBMITTER NAME: GALGO MEDICAL S.L
SUBMITTER ADDRESS: C/Comte d´Urgell 143, 4-B
08036 Barcelona
BARCELONA
SPAIN

CONTACT: Antoni Riu
TELEPHONE: +34 93 328 3964
e-mail: Antoni.riu@galgomedical.com

DEVICE TRADE NAME: ADAS 3D
COMMON NAME: Radiological Image Processing System
CLASSIFICATION NAME: Radiological Image Processing System (21 CFR 892.2050)
PRODUCT CODE: LLZ
REGULATION DESCRIPTION: Picture archiving and communications system

PREDICATE DEVICE(S): MR-CT VVA (K140587)

1. DEVICE DESCRIPTION

ADAS 3D is a software-based image processing tool for post-processing cardiovascular enhanced Magnetic Resonance (MRI) images and Computed Tomography Angiography (CTA) images.

ADAS 3D is designed to process DICOM image databases to enable the calculation, quantification and visualization of 3D cardiac imaging data by displaying and quantifying the levels of enhancement. ADAS 3D also enables the visualization of the shape of the cardiac chamber and the adjacent anatomy. After data processing, the data and images can be exported utilizing industry standard formats for viewing on other system, including Electrophysiology (EP) navigation system.

The following table lists the principal characteristics and features of the software:

Characteristics / Feature	ADAS 3D
General Features	
Operation System	Min. 64-bit Microsoft Windows 10 Rec. 64-bit Microsoft® Windows® 10
CPU Type	Min. Intel® Pentium® 4 or AMD Athlon™ 64, 3 GHz or faster or Intel® or AMD dual core 2 GHz or faster Rec. Intel® Core i74790 K or equivalent
Memory	Min. 8 GB RAM Rec. 16 GB RAM
Disk Space	Min. 100 GB free disk space for local study database Rec. 250 GB free disk space or more for local study database
Graphics	Min. Microsoft® DirectX 10® capable graphics card or higher

Section 5 – 510(k) Summary

	Rec. Microsoft® DirectX 11® or capable graphics card or higher (for example GeForce GT 730)
Other	1,280 x 1,024 or higher screen resolution
Input file formats	DICOM/DICOMDIR
System Interface	-DICOM: Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging. -LIEBRE Study: A LIEBRE study is a set of files storing each processed case. - Navigation System File Format: Format for Navigation system. Snapshots: Snapshots in PNG format. -Videos: Videos in MPEG format and MPEG-1 video codec.
User Interface	-Application workflow navigation tool. -Toolbar. -Working area. -Toolbox.
Functional Features	
Functions	-Importing Cardiac Imaging (MRI/CTA) in DICOM format **MRI Images support**: • Visualization of the distribution of the enhancement in a three-dimensional (3D) chamber of the heart • Quantification of the total volume of the enhancement within the Left Ventricle (LV) and the visualization of the enhancement area in multiple layers through the cardiac structure • Calculation, quantification and visualization of corridors of intermediate signal intensity enhancement in the LV • Quantification and visualization of the total area and distribution of the enhancement within the Left Atrium (LA) **CTA images support:** • Quantification of LV wall thickness • Identification and Visualization of other 3D anatomical structures - The ADAS 3D exports data into industry standard file formats supported by catheter navigation systems
Data Storage	All analysis results can be saved and reloaded again for reviewing and/or exporting. The analysis results include the input DICOM image, 3D models, numerical values, snapshots and videos.
Software Algorithms	-Left Ventricle Layer Computation -Left Atrium Layer Computation Algorithm -Enhancement Quantification algorithm -3D Corridor Detection Algorithm -Heart Anatomy Extraction algorithm -From Binary image to surface mesh algorithm -Left Ventricle Wall Thickness algorithm

Section 5 – 510(k) Summary

1.1. 3D corridors module

The 3D Corridors Module is an automatic detection feature designed to help identify and visualize 3D corridors of border zone (BZ) tissue within the LV. The 3D Corridors algorithm generates visual representations of the corridors that may travel through multiple layers of the LV.

A 3D Corridor is defined as a path of BZ tissue (or an area of intermediate intensity on the MRI) that starts and ends in healthy tissue (HT) and travels between areas of core scar (CS) tissue. A corridor is a three-dimensional path in the myocardium and has an associated volume. The ADAS 3D software distinguishes between protected and unprotected regions for a corridor.

- A protected region of BZ tissue is defined as the corridor that is embedded in an area of CS.
- An unprotected region of BZ tissue is defined as BZ tissue that is not surrounded by CS.

The ADAS 3D software only calculates 3D Corridors using the layers in between the endo and epicardium. The mitral value and the endo and epicardial surfaces define the boundaries for 3D Corridor detection, they are considered as CS tissue by the software.

To be automatically identified, by ADAS 3D, as a 3D Corridor, **four criteria** must be met in at least one layer:

1. It must pass through a BZ region
2. It must connect two HT regions
3. It must be **protected** by the CS region both
    a. Within its layer, on both sides and by a minimum CS size
    b. AND surrounding the layer
4. It must have a minimum length of 5 mm

1.1.1. Precautions

- The software is not intended to identify regions for catheter ablation or treatment of arrhythmias.
- This software is a tool to support clinicians for better visualization of cardiac images from MR and CTA. It is up to the clinicians to make their own interpretations of the information that is presented.
- The intermediate signal intensity “3D Corridor” detection tool is not intended for clinical patient management and its use has not been validated clinically.
- The results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis.

1.2. SUMMARY OF COMPARISON WITH PREDICATE DEVICE

In the establishment of substantial equivalence, the Software ADAS 3D is compared with the following previously cleared device:

- MR-CT VVA (K140587)

Section 5 – 510(k) Summary

Comparison of the proposed devices with the predicate device is summarized in the following table

Elements of Comparison	Proposed Device ADAS 3D (GALGO MEDICAL S.L)	Predicate Device MR-CT VVA (Medis Medical Imaging Systems, b.v.)	
Regulatory Data			
Regulatory Class	Class II	Class II	Identical
Classification name	Radiological Image processing system	Radiological Image processing system	Identical
Regulation Number	21 CFR 892.2050	21 CFR 892.2050	Identical
Product Code	LLZ	LLZ	Identical
FDA Clearance	Pending	510(k) cleared: K140587	-
Use			
Indication for Use	ADAS 3D is indicated for use in the clinical setting to support the visualization and analysis of cardiac MR and CTA images for patients with cardiovascular disease. ADAS 3D is indicated for patients with myocardial scar produced by ischemic or non-ischemic heart disease. ADAS 3D processes MR and CTA images. The quality and the resolution of the original images determines the quality and the accuracy of the data produced by ADAS 3D. ADAS 3D is indicated to be used by qualified medical professionals (cardiologists, electrophysiologists, radiologists or trained technicians) for the calculation, quantification and visualization of cardiac images. The data produced by ADAS 3D is indicated to be used to support clinical decision making and should not be used on an irrefutable basis or as the sole source of information for	MR-CT VVA is indicated for use in clinical settings where more reproducible than manually derived quantified results are needed to support the visualization and analysis of MR and CT images of the heart and blood vessels for use on individual patients with cardiovascular disease. Further, MR-CT VVA allows the quantification of cerebral spinal fluid in MR velocity-encoded flow images. When the quantified results provided by MR-CT VVA are used in a clinical setting on MR and CT images of an individual patient, they can be used to support the clinical decision making for the diagnosis of the patient. In this case, the results are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis, and they are only intended for use by the responsible clinicians.	Similar to predicate device

Section 5 – 510(k) Summary

Elements of Comparison	Proposed Device ADAS 3D (GALGO MEDICAL S.L)	Predicate Device MR-CT VVA (Medis Medical Imaging Systems, b.v.)	
	clinical diagnosis or patient treatment. ADAS 3D is not intended to identify regions for catheter ablation or treatment of arrhythmias.		

Section 5 – 510(k) Summary

Intended use	ADAS 3D is intended to be used for post-processing cardiovascular enhanced Magnetic Resonance (MR) images and Computed Tomography Angiography (CTA) images that are formatted in Digital Imaging and Communication in Medicine (DICOM) standard. ADAS 3D is intended for the non-invasive calculation, quantification and visualization of cardiac imaging data to support a comprehensive diagnostic decision-making process for understanding cardiovascular disease. ADAS 3D analyzes the enhancement of myocardial fibrosis from DICOM MR images to support: • Visualization of the distribution of the enhancement in a three-dimensional (3D) chamber of the heart. • Quantification of the total volume of the enhancement within the left Ventricle (LV) and the visualization of the enhancement area in multiple layers through the cardiac structure. • Calculation, quantification and visualization of corridors of intermediate signal intensity enhancement in the LV. • Quantification and visualization of the total area and distribution of the enhancement within the Left Atrium (LA). Additionally, ADAS 3D imports DICOM CTA images to support: • Quantification of the wall thickness of the LV.	QMass® MR is software intended to be used for the visualization and analysis of MR and CT images of the heart and blood vessels. QMass® MR is intended to support the following visualization functionalities: - cine loop and 2D review - performing caliper measurements QMass® MR is also intended to support the following analyses: - cardiac function quantification - anatomy and tissue segmentation - signal intensity analysis for the myocardium and infarct sizing - MR parametric maps (such as T1, T2, T2* relaxation) QMass® MR is also intended to be used for: - quantification of T2* results in MR images that can be used to characterize iron loading in the heart and the liver These analyses are based on contours that are either manually drawn by the clinician or trained medical technician who is operating the software, or automatically detected by the software and subsequently presented for review and manual editing. The results obtained are displayed on top of the images and provided in reports. The analysis results obtained with QMass® MR are intended for use by cardiologists and radiologists to support clinical decisions concerning the heart and vessels.	Similar to predicate device

Section 5 – 510(k) Summary

Elements of Comparison	Proposed Device ADAS 3D (GALGO MEDICAL S.L)	Predicate Device MR-CT VVA (Medis Medical Imaging Systems, b.v.)	
	• Identification and visualization of other 3D anatomical structures. ADAS-3D exports information to multiple industry standard file formats suitable for documentation and information sharing purposes. The 3D data is exported into industry standard file formats supported by catheter navigation systems. It is intended to be used by qualified medical professionals (cardiologists, electrophysiologists, radiologists or trained technicians) experienced in examining and evaluating cardiovascular MR and CTA images as part of the comprehensive diagnostic decision-making process. ADAS-3D is a standalone software application.		
Technical characteristics			
General description	Is a software solution for the visualization and analysis of cardiovascular MR and CT images.	Is software intended to be used for the visualization and analysis of MR and CT images of the heart and blood vessels.	Identical to predicate device
Mode of action	Software Solution	Software Solution	Identical to predicate device
Operating System	Windows	Windows	Identical to predicate device
Principles of operation	Analysis of MR and CT images	Analysis of MR and CT images	Identical to predicate device
User Interface	Mouse, Keyboard	Mouse, Keyboard	Identical to predicate device
Target Population	Patients with myocardial scar.	Individual patients with cardiovascular disease.	Similar to predicate device
Anatomical	Left Ventricle and Left Atrium	Left ventricle and Right Ventricle	Similar than

Section 5 – 510(k) Summary

Elements of Comparison	Proposed Device ADAS 3D (GALGO MEDICAL S.L)	Predicate Device MR-CT VVA (Medis Medical Imaging Systems, b.v.)	
sites			predicate device
Conditions of use	It is intended to be used by qualified medical professionals (cardiologists, radiologists or trained technicians) experienced in examining and evaluating cardiovascular MR and CTA images as part of the comprehensive diagnostic decision-making process.	Must be used by Cardiologist, radiologist or trained technicians who are qualified to perform cardiac analysis.	Identical to predicate device
Images supported	Vendor independent DICOM MR/CT images (specific requirements depends on type of analysis, but imaging viewing is possible on all MR/CT images)	Vendor independent DICOM MR/CT images (specific requirements depend on type of analysis, but imaging viewing is possible on all MR/CT images)	Identical to predicate device
Image Features			
Image assessment	By visualization and analysis of the images	By visualization and analysis of the images	Identical to predicate device
Image display and manipulation	- 2D slice review - 3D Multiplanar reconstruction - Pan/zoom; magnify; maximize and minimize; scroll through slice stack; adjust window level, contrast and brightness.	- 2D slice review - 3D Multiplanar reconstruction - Pan/zoom; magnify; maximize and minimize; scroll through slice stack; adjust window level, contrast and brightness. - Cine loop - Performing caliper measurements	Similar to predicate device
Result visualization	- Numerical - Graph - 2D view - 3D view	- Numerical - Graph - Bulls Eye View - 2D view - 3D view	Similar to predicate device
Export capabilities	- Snapshots as PNG - Videos as MPEG - Numerical data as TXT - Study data as an internal file format	- Images, movie frames, movies, graphs, snapshots and reports in various file formats or as DICOM secondary captures - Reports can be exported in TXT, PDF, HTML, XML and as DICOM SC directly to PACS	Similar to predicate device

Section 5 – 510(k) Summary

Elements of Comparison	Proposed Device ADAS 3D (GALGO MEDICAL S.L)	Predicate Device MR-CT VVA (Medis Medical Imaging Systems, b.v.)	
	- 3D surface meshes as VTK/DIF	- All analysis results can be saved and reloaded again for reviewing and/or exporting	
Performing Function Analysis			
	- Quantification of LV wall thickness	Cardiac Function Quantification: mass, wall motion, wall thickness and wall thickening	Similar to predicate device
	- Identification and Visualization of other 3D anatomical structures	Anatomy and tissue segmentation	Similar to predicate device
	- Visualization of the distribution of the enhancement in a three-dimensional (3D) chamber of the heart. - Quantification of the total volume of the enhancement within the Left Ventricle (LV) and the visualization of the enhancement area in multiple layers through the cardiac structure. - Calculation, quantification and visualization of corridors of intermediate, signal intensity enhancement in the LV.	Signal intensity analysis for the myocardium and infarct sizing. Also referred as DSI (Delayed Signal Intensity)	Similar to predicate device (see detailed comparison in the section below)
	None	MR parametric maps (such as T1, T2, T2* relaxation)	N/A (additional specifications for the predicate device, not included on the proposed device)

Section 5 – 510(k) Summary

Elements of Comparison	Proposed Device ADAS 3D (GALGO MEDICAL S.L)	Predicate Device MR-CT VVA (Medis Medical Imaging Systems, b.v.)	
	None	quantification of T2* results in MR images that can be used to characterize iron loading in the heart and the liver	N/A (additional specifications for the predicate device, not included on the proposed device)
Performance function analysis of enhancement			
	Visualization of the enhancement in 2D	Visualization of the DSI in 2D	Similar to predicate device
	Visualization of the distribution of the enhancement in a three-dimensional (3D) chamber of the heart.	Visualization of the DSI in 3D	Similar to predicate device
	- Quantification of the total volume of the enhancement within the Left Ventricle (LV) and the visualization of the enhancement area in multiple layers through the cardiac structure. - Quantification and visualization of the total area and distribution of the enhancement within the left Atrium (LA) Measurements: - Total Volume (g), BZ (g) and Core (g) - For each layer: Total area (cm2), BZ (cm2) and Core (cm2)	Quantification of DSI Measurements: - Quantification of infarct size (% and mass), infarct transmurality	Similar to predicate device
	- Calculation, quantification and visualization of corridors of	Visualization of DSI	Similar to predicate

Section 5 – 510(k) Summary

Elements of Comparison	Proposed Device ADAS 3D (GALGO MEDICAL S.L)	Predicate Device MR-CT VVA (Medis Medical Imaging Systems, b.v.)	
	intermediate, signal intensity enhancement in the LV.		device

Table 5.1 Summary comparison of characteristics and features – proposed and predicate devices.

Section 5 – 510(k) Summary

1.3. INTENDED USE

As established in the Indications for Use Statement:

ADAS 3D is indicated for use in the clinical setting to support the visualization and analysis of cardiac MR and CTA images for patients with cardiovascular disease.

ADAS 3D is indicated for patients with myocardial scar produced by ischemic or non-ischemic heart disease.

ADAS 3D processes MR and CTA images. The quality and the resolution of the original images determines the quality and the accuracy of the data produced by ADAS 3D.

ADAS 3D is indicated to be used by qualified medical professionals (cardiologists, electrophysiologists, radiologists or technicians) for the calculation, quantification and visualization of cardiac images. The data produced by ADAS 3D is indicated to be used to support clinical decision making and should not be used on an irrefutable basis or as the sole source of information for clinical diagnosis or patient treatment. The data produced by ADAS 3D is intended to be used to support qualified medical professionals for clinical decision making.
ADAS 3D is not intended to identify regions for catheter ablation or treatment of arrhythmias.

ADAS 3D has similar intended uses as the predicate devices and has very similar technological characteristics. However, subject and predicate devices have some minor different technical characteristics as described in Section 12 of this submission.

1.4. SUMMARY DISCUSSION OF NON-CLINICAL DATA

The proposed device has been designed, developed, tested, verified and validated according to documented procedures and specific protocols in line with the FDA guidance documents.

Non-clinical test data are submitted to support this premarket notification and to establish the decision concerning adequate safety and performance of the predicate device. It was tested and validated with synthetic and phantom data. The results of these non-clinical data testing and validation is included in this submission in section 18.

The FDA guidance documents used are the following:

- Guidance for the Submission of Premarket Notifications for Medical Imaging Management Devices
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- Guidance for Off-The-Shelf Software Use in Medical Devices – September 9, 1999
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff – January

11, 2002.

- Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices – September 6, 2017
- Design and development included identification, evaluation and control of potential hazards as per standard ISO 14971. Integration, verification and validation testing have been successfully completed following standard ISO 62304.

1.5. SUMMARY DISCUSSION OF CLINICAL DATA

Clinical data was used to test and validate this software as described in section 18 of this submission to support this premarket notification and to establish the decision concerning adequate safety and performance of the predicate device.

1.6. CONCLUSIONS

We believe the intended use, the indications for use and performance of the ADAS 3D software is substantially equivalent to the intended use, indications for use and performance of the predicate device. We also believe that the ADAS 3D software does not pose any new or increased risk compared with the predicate device. Based on the information included in this submission, we conclude that ADAS 3D is substantially equivalent to the listed legally marketed predicate devices.