Adas3D Medical S.L.
% Antonio Riu
General Manager
Paris 179, 2-2
Barcelona, Barcelona 08036
SPAIN

April 5, 2021

Re: K210850
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: March 17, 2021
Received: March 22, 2021

Dear Antonio 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,

Michael D. O'Hara 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210850

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 (cardiologists, electrophysiologists, radiologists or trained technicians) for the calculation, quantification and visualization of cardiac images and intended to be used for pre-planning and during electrophysiology procedures. 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.

The clinical significance of using ADAS 3D to identify arrhythmia substrates for the treatment of cardiac arrhythmias (e.g., ventricular tachycardia) or risk stratification has not been established.

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

K210850

SUBMITTER NAME: ADAS3D MEDICAL S.L
SUBMITTER ADDRESS: C/ Paris 179, 2º-2º
08036 Barcelona
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SPAIN

CONTACT: Antoni Riu
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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): ADAS 3D (K191125)

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 systems, including Electrophysiology (EP) navigation systems.

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 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

2. 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

3. SUMMARY OF COMPARISON WITH PREDICATE DEVICE

The ADAS 3D device that is the subject of this Special 510(k) is identical to the ADAS 3D device cleared under (K191125). Only clarifications to the Indications for Use and Precautions sections have been made as noted with use of bold (added language) and strikethrough (deleted language) fonts in the following table. These labelling changes do not impact the safety or effectiveness of the device.

Elements of Comparison	Predicate Device ADAS 3D (ADAS3D MEDICAL S.L) K191125	Modified Device ADAS 3D (ADAS3D MEDICAL S.L)
Regulatory Data		
Regulatory Class	Class II	Class II
Classification name	Radiological Image processing system	Radiological Image processing system
Regulation Number	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ	LLZ
510(k) Number	K191125	To be assigned
Use		
Indication for Use	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 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 **(cardiologists, electrophysiologists, radiologists or trained technicians) for the calculation, quantification** and visualization of cardiac images **and intended to be used for pre-planning and during electrophysiology procedures**. The data produced by ADAS 3D must not be used as an irrefutable basis or a source of medical

Elements of Comparison	Predicate Device ADAS 3D (ADAS3D MEDICAL S.L) K191125	Modified Device ADAS 3D (ADAS3D MEDICAL S.L)
	ADAS 3D is not intended to identify regions for catheter ablation or treatment of arrhythmias.	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.~~ **The clinical significance of using ADAS 3D to identify arrhythmia substrates for the treatment of cardiac arrhythmias (e.g., ventricular tachycardia) or risk stratification has not been established.**
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.	~~• 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. • **The software has not been validated for identifying arrhythmia substrates and should not be used as the sole source of information for treatment planning.** • **The clinical significance of using the software to identify arrhythmia substrates for the treatment of cardiac arrhythmias (e.g., ventricular**

Elements of Comparison	Predicate Device ADAS 3D (ADAS3D MEDICAL S.L) K191125	Modified Device ADAS 3D (ADAS3D MEDICAL S.L)
		tachycardia) or risk stratification has not been established.
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. • 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	No change

Elements of Comparison	Predicate Device ADAS 3D (ADAS3D MEDICAL S.L) K191125	Modified Device ADAS 3D (ADAS3D MEDICAL S.L)
	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. The target population of the use of ADAS-3D is not restricted	
Technical characteristics		
General description	Is a software solution for the visualization and analysis of cardiovascular MR and CT images.	No change
Mode of action	Software Solution	No change
Operating System	Windows	No change
Principles of operation	Analysis of MR and CT images	No change
User Interface	Mouse, Keyboard	No change
Target Population	Patients with myocardial scar.	No change
Anatomical sites	Left Ventricle and Left Atrium	No change
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.	No change
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)	No change
Image Features		
Image assessment	By visualization and analysis of the images	No change

Elements of Comparison	Predicate Device ADAS 3D (ADAS3D MEDICAL S.L) K191125	Modified Device ADAS 3D (ADAS3D MEDICAL S.L)
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.	No change
Result visualization	- Numerical - Graph - 2D view - 3D view	No change
Export capabilities	- Snapshots as PNG - Videos as MPEG - Numerical data as TXT - Study data as an internal file format - 3D surface meshes as VTK/DIF	No change
Performing Function Analysis		
	- Quantification of LV wall thickness	No change
	- Identification and Visualization of other 3D anatomical structures	No change
	- 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.	No change
Performance function analysis of enhancement		
	Visualization of the enhancement in 2D	No change
	Visualization of the distribution of the enhancement in a three-dimensional (3D) chamber of the heart.	No change
	- 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)	No change

Elements of Comparison	Predicate Device ADAS 3D (ADAS3D MEDICAL S.L) K191125	Modified Device ADAS 3D (ADAS3D MEDICAL S.L)
	and Core (cm2)	
	- Calculation, quantification and visualization of corridors of intermediate, signal intensity enhancement in the LV.	No change

4. INDICATIONS FOR USE

The revised Indications for Use are as follows:

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 (cardiologists, electrophysiologists, radiologists or trained technicians) for the calculation, quantification and visualization of cardiac images and intended to be used for pre-planning and during electrophysiology procedures. 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.

The clinical significance of using ADAS 3D to identify arrhythmia substrates for the treatment of cardiac arrhythmias (e.g., ventricular tachycardia) or risk stratification has not been established.

5. CONCLUSIONS

The clarifications to the Indications for Use and Precautions sections of the labelling do not impact the safety or effectiveness of the device. Therefore, the subject ADAS 3D software device is substantially equivalent to the ADAS 3D device cleared in K191125.