Adas3D Medical S.L
Antoni Riu
General Manager
Rambla Catalunya 53, 4H
Barcelona, Barcelona 08007
Spain

May 23, 2023

Re: K230803
Trade/Device Name: Adas 3d
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: May 12, 2023
Received: May 12, 2023

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,

Jessica Lamb
Assistant Director
Imaging Software Team
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

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)*
K230803

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.

510(K) SUMMARY

SUBMITTER NAME: ADAS3D MEDICAL S.L
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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: ADAS 3D (K212421)

1. DEVICE DESCRIPTION

ADAS 3D is a software tool intended to be used for post-processing cardiovascular enhanced Magnetic Resonance (MR) images and Computed Tomography Angiography (CTA) images that are formatted in the 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 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.

ADAS 3D analyses 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 LV wall thickness.
- Identification and Visualization of other 3D anatomical structures.
- Quantification and visualization of LA wall thickness.
- Quantification and visualization of distances from the LA epicardium to other 3D anatomical structures.

Additionally, ADAS 3D imports DICOM Magnetic Resonance Angiography (MRA) images to support:

- Identification and Visualization of other 3D anatomical structures.

It is designed 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.

2. INDICATIONS 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 (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.

3. COMPARISON WITH PREDICATE DEVICE

The ADAS 3D device that is the subject of this Special 510(k) contains seven modifications compared to the previous version of the ADAS 3D cleared under K212421. Only one of the seven modifications impacts the existing device description denoted in **bold text** in the left column in the table below.

Elements of Comparison	Modified Device ADAS 3D (ADAS3D MEDICAL S.L)	Predicate Device ADAS 3D (ADAS3D MEDICAL S.L) K212421
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	To be assigned	K212421
Use		
Indications 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 (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	No change

Elements of Comparison	Modified Device ADAS 3D (ADAS3D MEDICAL S.L)	Predicate Device ADAS 3D (ADAS3D MEDICAL S.L) K212421
	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.	
Device Description Including Functional and Technological Characteristics	ADAS 3D is a software tool intended to be used for post-processing cardiovascular enhanced Magnetic Resonance (MR) images and Computed Tomography Angiography (CTA) images that are formatted in the 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 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. ADAS 3D analyses the enhancement of myocardial fibrosis from DICOM MR images to support: - Visualization of the distribution of the enhancement in a three-dimensional	ADAS 3D is a stand-alone software tool designed for post-processing cardiovascular enhanced Magnetic Resonance (MR) images and Computed Tomography Angiography (CTA) images that are formatted in the Digital Imaging and Communication in Medicine (DICOM) standard. ADAS 3D software aids in 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 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. ADAS 3D analyses the enhancement of myocardial fibrosis from DICOM MR images to support: - Visualization of the distribution of the enhancement in a three-dimensional

Elements of Comparison	Modified Device ADAS 3D (ADAS3D MEDICAL S.L)	Predicate Device ADAS 3D (ADAS3D MEDICAL S.L) K212421
	(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 LV wall thickness. - Identification and Visualization of other 3D anatomical structures. - Quantification and visualization of LA wall thickness. - Quantification and visualization of distances from the LA epicardium to other 3D anatomical structures. **Additionally, ADAS 3D imports DICOM Magnetic Resonance Angiography (MRA) images to support:** - **Identification and Visualization of 3D anatomical structures.** 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	(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 LV wall thickness. - Identification and Visualization of other 3D anatomical structures. - Quantification and visualization of LA wall thickness. - Quantification and visualization of distances from the LA epicardium to other 3D anatomical structures. It is designed 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

Changes from the last 510(k) clearance K212421:

No.	Changes(s)
1.	**Change-1: Initial identification of structures** - The Heart Anatomy Extraction tool has been improved with an option to provide an initial identification of the coronaries. - The Left Ventricle Enhancement analysis has been improved with an option to provide an initial identification of the Left Ventricle. - The Heart Anatomy Extraction tool has been improved with an option to provide an initial identification of the left chambers and aorta.
2.	**Change 2: Improved Export Formats** - The export to the DIF-5.0 file format has been optimized to preserve the transition of the three tissue types for the exported layers. - The functionality to export to catheter navigation systems has been improved to add support to the Navigant navigation system from the manufacturer Stereotaxis Inc. (St Louis, MO, USA) and the Rhythmia HDx navigation system from the manufacturer Boston Scientific Corporation (Minneapolis, MN, USA).
3.	**Change 3: Addition of measurements tools** A generic Measurement Module has been added to allow computing distances between points.
4.	**Change 4: Improved left ventricle Wall Thickness Workflow for CTA.** The Left Ventricle Wall Thickness analysis has been improved to obtain a more detailed segmentation of the patient anatomy and a better visualization of the thickness for CTA images.
5.	**Change 5: Improve in corridor detection** The 3D Corridors detection module has been improved to handle special cases for the treatment of the Healthy Tissue (HT) region.
6.	**Change 6: Import of MRA DICOM images** The DICOM import tool has been improved to add support for the MRA image modality.
7.	**Change 7: Exclude image region** The calculation, quantification and visualization of cardiac imaging data has been improved by adding an Exclude Image Region Tool to allow excluding a region from analysis.

4. SUMMARY OF NON-CLINICAL TESTING

The modified ADAS 3D device has been subject to design controls including design review, risk analyses, design verification / validation testing in order to ensure its safety and effectiveness. The modifications were assessed using well-established methods to validate that the software fully satisfies system requirements.

5. CONCLUSION

The implemented design control activities demonstrate the safety and effectiveness of the

modified device. Therefore, Adas3D Medical believes the modified ADAS 3D software device should be found substantially equivalent to the predicate ADAS 3D device (K212421).