September 9, 2024

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

Re: K240791
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: QIH, LLZ
Dated: August 9, 2024
Received: August 9, 2024

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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Jessica Lamb, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240791

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.

Adas3D Medical	**510(k) Summary K240791**

1 General Information

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

DATE:	September 9, 2024
SUBMITTER:	Adas3D Medical S.L. Rambla Catalunya 53, 4-H 08036 Barcelona Barcelona Spain
CONTACT:	Antoni Riu +34 93 328 3964 antoni.riu@adas3d.com
DEVICE TRADE NAME:	ADAS 3D
COMMON NAME:	Radiological Image Processing System
CLASSIFICATION NAME:	Radiological Image Processing System (21 CFR 892.2050)
PRODUCT CODE:	Primary product code: QIH Secondary product code: LLZ
REGULATION DESCRIPTION:	Picture archiving and communications system
PREDICATE DEVICE:	ADAS 3D (K230803)

2 Device Description

ADAS 3D is a stand-alone 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 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 (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.

Additionally, ADAS 3D uses the following machine-learning-based features:

- Standard Initialization of the LV, LA, and Aorta from CTA
- Standard Initialization of the Coronary Arteries from CTA
- Standard Initialization of the LA from CTA
- Standard Initialization of the LV from 2D LGE-MRI and Automatic Slice Alignment
- Standard Initialization of the LV from 3D LGE-MRI
- Standard Initialization of the LA from 3D LGE-MRI

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.

3 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.

4 Comparison with Predicate Device

Adas3D Medical SL is modifying its own device [ADAS 3D; K230803] under this traditional 510(k). The purpose of this submission is to make three (3) modifications to the device. The following two tables compare the Indications for Use, Device Description (including functional and technological characteristics) and the new modifications of the subject device to the predicate device.

Elements of Comparison	**Subject Device** **ADAS 3D** **(Adas3D Medical S.L.)**	**Predicate Device** **ADAS 3D** **(K230803)**
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	QIH, LLZ	LLZ
510(k) Number	K240791	K230803
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 procedures. The data	Same

Elements of Comparison	Subject Device ADAS 3D (Adas3D Medical S.L.)	Predicate Device ADAS 3D (K230803)
	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 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:	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:

Elements of Comparison	Subject Device ADAS 3D (Adas3D Medical S.L.)	Predicate Device ADAS 3D (K230803)
	• 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.	• 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

Elements of Comparison	Subject Device ADAS 3D (Adas3D Medical S.L.)	Predicate Device ADAS 3D (K230803)
	Additionally, ADAS 3D uses the following machine-learning-based features: ● Standard Initialization of the LV, LA, and Aorta from CTA ● Standard Initialization of the Coronary Arteries from CTA ● Standard Initialization of the LA from CTA ● Standard Initialization of the LV from 2D LGE-MRI and Automatic Slice Alignment ● Standard Initialization of the LV from 3D LGE-MRI ● Standard Initialization of the LA from 3D LGE-MRI 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.	trained technicians) experienced in examining and evaluating cardiovascular MR and CTA images as part of the comprehensive diagnostic decision-making process.

5 Changes from the predicate device

Feature	Subject Device ADAS 3D (Adas3D Medical S.L.)	Predicate Device ADAS 3D (Adas3D Medical S.L.) (K230803)	Comparison
Supported Operating Systems	Linux RHEL 8, Windows 11 and Windows 10	Windows 10	Added support for Linux RHEL 8 and Windows 11
Initial Identification of structures	Semi-automatic using Machine Learning technique: ● Left Chambers from CTA ● Left Ventricle from 2D DE-MRI ● Coronaries from CTA ● Left Ventricle from 3D DE-MRI ● Left Atrium from 3D DE-MRI ● Left Atrium Wall Thickness from CTA	Semi-automatic using Machine Learning technique: ● Left Chambers from CTA ● Left Ventricle from 2D DE-MRI ● Coronaries from CTA Manual: ● Left Ventricle from 3D DE-MRI ● Left Atrium from 3D DE-MRI ● Left Atrium Wall Thickness from CTA	Added three new semi-automatic segmentations using Machine Learning technique. Improved the already existing three semi-automatic segmentations.

6 Summary of Non-Clinical Testing

The subject device has undergone design reviews, risk analyses, and verification and validation testing, to ensure its safety and effectiveness. The subject device has been assessed using well-established methods to validate that is substantial equivalent to the predicate device.

6.1 Machine Learning features

The machine-learning features were trained and tested using DICOM data from several clinical sites from multiple countries. The DICOM data was acquired using a variety of CT/MRI scanners and scanner protocols from different manufacturers.

This DICOM data was anonymized by the hospitals before being sent to us, in compliance with the European General Data Protection Regulation (GDPR). This anonymization process prevented including personal patient information such as gender, age, or ethnicity.

This DICOM dataset includes a diverse range of atrial and ventricular conditions. The Left Ventricle (LV) includes ischemic and non-ischemic cardiomyopathies such as left ventricular hypertrophy and dilated cardiomyopathy, as well as other cardiac conditions like premature ventricular contractions. The Left Atrium (LA), includes a diverse range of conditions and presentations, from relatively healthy atrial tissue to various forms of atrial fibrillation (paroxysmal, persistent, long-standing persistent, and recurrent cases), other atrial

pathologies such as atrial flutter and atrial tachycardia, and structural heart diseases impacting left atrial function.

6.1.1 Training

For each machine learning feature, the training dataset has been obtained from the initial DICOM dataset, according to the image modality and the target structure. All DICOM images are from European hospitals. The details of the training dataset for each machine learning feature are summarized in the table below.

Machine learning feature	Number of DICOM images	Scanner manufacturers
Standard Initialization of the Left Chambers and Aorta from CTA	111	GE (62%), Toshiba (35%), Philips (3%)
Standard Initialization of the Coronaries from CTA	231	Toshiba (48%), Siemens (37%), GE (14%) and Philips (1%).
Standard Initialization the LA from CTA	136	GE (65%), Toshiba (32%) and Philips (3%)
Standard Initialization LV from 2D DE-MRI	126	Siemens (91%), GE (6%), Phillips (3%)
Standard Initialization of the LV from 3D DE-MRI	110	Siemens (99%), GE (1%)
Standard Initialization of the LA from 3D DE-MRI	82	GE (51%), Philips (49%)

The DICOM dataset has been annotated identifying the target structures. The annotation of the data was generated initially by the hospitals' clinical teams and revised by Adas3D Medical's Clinical Team. The Adas3D Medical's Clinical Team consists of highly experienced individuals with knowledge of cardiac anatomy, interpretation of MRI and CT volumes, and the use of ADAS 3D.

6.1.2 Performance testing

The performance testing for each machine learning feature was performed using a subset of the initial DICOM dataset, that was selected according to the target structure, the image modality, the country, and the scan manufacturer. Each testing dataset has been selected from hospitals not used in any stage of algorithm development, including training. The details of each testing dataset are summarized in the table below.

Machine learning feature	Number of cases	Data sources	Scanner manufacturers
Standard Initialization of the Left Chambers	100	US (62%) and	US: SIEMENS (61%), Toshiba (32%) and GE (7%)

and Aorta from CTA		OUS (38%)	OUS: SIEMENS (47%), Toshiba (26%), Canon (13%), GE (11%) and Philips (3%)
Standard Initialization of the Coronaries from CTA	100	US (64%) and OUS (36%)	US: SIEMENS (64%), Toshiba (26%), GE (8%) and Phillips (2) OUS: SIEMENS (47%), Toshiba (28%), Canon (14%), GE (8%) and Philips (3%)
Standard Initialization the LA from CTA	100	US (65%) and OUS (35%)	US: SIEMENS (58%), Toshiba (34%) and GE (8%) OUS: SIEMENS (53%), Toshiba (30%), Canon (11%), GE (3%) and Philips (3%)
Automatic Slice Alignment for LV from 2D DE-MRI	70	US (52%) and OUS (48%)	US: SIEMENS (72%), Philips (25%) and GE (3%) OUS: Philips (58%), SIEMENS (18%) and GE (24%)
Standard Initialization of the LV from 2D DE-MRI	100	US (52%) and OUS (48%)	US: SIEMENS (71%), Philips (23%) and GE (6%) OUS: Philips (50%), SIEMENS (19%) and GE (31%)
Standard Initialization of the LV from 3D DE-MRI	100	US (69%) and OUS (31%)	US: SIEMENS (62%), Philips (32%) and GE (6%) OUS: SIEMENS (49%), Philips (45%), Toshiba (3%) and GE (3%)
Standard Initialization of the LA from 3D DE-MRI	95	US (60%) and OUS (35%)	US: Philips (50%), SIEMENS (45%) and GE (5%) OUS: SIEMENS (71%), Philips (26%) and GE (3%)

Ground truth annotations were generated using the manual tools of the FDA-cleared ADAS 3D software by two clinical experts independent of the clinical experts who established the ground truth of the training dataset.

The performance metrics and the acceptance criteria for each target structure are based on a review of state-of-the-art algorithms. Performance testing follows a non-inferiority approach, with a predefined non-inferiority margin. The primary goal of ADAS 3D is to provide a preliminary initialization of the target structure, which would then be subject to further refinement by the user. This non-inferiority approach confirms that the performance aligns with the average performance benchmarks reported in the field.

The following metrics have been used to define the acceptance criteria:

- MSD: Mean Surface Distance.
- HD: Hausdorff Distance.
- MDS: Mean Difference in Shifts computes the slice alignment error between two 2D MRI images. It is computed as the mean of the shifts in x and y dimensions for all slices.

- APD: The Average Perpendicular Distance measures the average distance (in mm) of all corresponding contour points between two contours. A low APD value means that the two contours match closely.
- DC: Dice Metric.
- Color agreement (CA), Color disagreement by one color (CD1), and Color disagreement by two colors or more (CD2): These three metrics are defined in the paper: Valles-Colomer, A., Rubio Forcada, B., Soto-Iglesias, D. et al. Reproducibility analysis of the computerized tomography angiography–derived left atrial wall thickness maps. J Interv Card Electrophysiol 66, 1045–1055 (2023). https://doi.org/10.1007/s10840-023-01472-5

The table below summarizes the performance results. The metric values used for evaluating the performance are highlighted in bold.

Machine Learning feature	Target structure	Metric	Mean	Lower CI95	Higher CI95	Threshold	Meets acceptance criteria
Standard Initialization of the Left Chambers and Aorta from CTA	LV	DC	0.93	**0.92**	0.94	**0.84**	yes
	LV	MSD	1.29	1.03	**1.56**	**2.23**	yes
	LA	DC	0.94	**0.94**	0.95	**0.84**	yes
	LA	MSD	1.06	0.95	**1.17**	**2.23**	yes
	AO	DC	0.94	**0.94**	0.95	**0.84**	yes
	AO	MSD	0.93	0.51	**1.34**	**2.23**	yes
	LAA	DC	0.84	**0.83**	0.85	**0.76**	yes
	LAA	MSD	1.01	0.91	**1.1**	**2.23**	yes
Standard Initialization of the Coronary Arteries from CTA	LCA	DC	0.82	**0.80**	0.84	**0.78**	yes
	LCA	HD	7.71	6.05	**9.37**	**10.86**	yes
	RCA	DC	0.82	**0.80**	0.83	**0.78**	yes
	RCA	HD	6.61	5.24	**7.97**	**10.86**	yes
Standard Initialization of the LA from CTA	LA ENDO	MSD	0.37	0.32	**0.41**	**0.32**	no
	LA EPI	MSD	0.56	0.51	**0.61**	**0.76**	yes
	LA	CA	56.09	**53.56**	58.63	**43.90**	yes
	LA	CD1	38.32	36.37	**40.28**	**49.00**	yes
	LA	CD2	5.58	4.73	**6.44**	**12.10**	yes
Automatic Slice Alignment for LV from 2D LGE-MRI	LV	MDS	2.39	2.22	**2.55**	**6.23**	yes
Standard Initialization of	LV ENDO	DC	0.90	**0.90**	0.91	**0.85**	yes
	LV ENDO	APD	2.01	1.89	**2.13**	**2.10**	no
	LV ENDO	HD	9.72	9.04	**10.40**	**13.25**	yes

the LV from 2D LGE-MRI	LV EPI	DC	0.93	**0.93**	0.94	**0.89**	yes
	LV EPI	APD	2.06	1.95	**2.17**	**1.93**	no
	LV EPI	HD	9.81	9.11	**10.51**	**13.25**	yes
Standard Initialization of the LV from 3D LGE-MRI	LV ENDO	DC	0.88	**0.87**	0.88	**0.79**	yes
	LV ENDO	HD	2.40	2.15	**2.64**	**27.32**	yes
	LV EPI	DC	0.91	**0.90**	0.92	**0.78**	yes
	LV EPI	HD	9.57	8.81	**10.33**	**27.32**	yes
Standard Initialization of the LA from 3D LGE-MRI	LA	DC	0.90	**0.89**	0.91	**0.86**	yes
	LA	MSD	1.62	1.45	**1.78**	**1.39**	no
	LA	HD	12.36	11.17	**13.55**	**16.50**	yes

Four tests did not meet the non-inferiority criteria. In these four cases, the discrepancies are sub-pixel, indicating that our algorithm's performance is acceptable given the minimum pixel spacing of the input images.

A subgroup analysis found that the algorithms' performance is consistent across US and OUS groups.

6.1.3 Performance testing conclusion

The results of the performance testing confirm that the subject device met all acceptance criteria and demonstrate that the performance of the machine learning features is in line with the performance of the predicate device.

7 Conclusion

The comparison of the subject device with the predicate device show that they have substantially equivalent indications for use, functional and technological characteristics.

Adas3D Medical believes the subject device is substantially equivalent to the predicate device and is as safe and effective as the predicate device.