



September 30, 2026

Medical AI Co., Ltd.
Suzanne Goodman
RA Leader
13th Floor, 38, Yeongdong-Daero 85-Gil
Gangnam-Gu, Seoul, 06180
Republic Of Korea

Re: K254302

Trade/Device Name: AiTiALVSD
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular Machine Learning-Based Notification Software
Regulatory Class: Class II
Product Code: QYE
Dated: September 5, 2026
Received: September 8, 2026

Dear Goodman Suzanne:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding

When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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

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

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

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

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

Sincerely,

STEPHEN C. BROWNING -S

CDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K254302

Device Name

AiTIALVSD

Indications for Use (Describe)

AiTIALVSD is a software that utilizes artificial intelligence (AI) algorithms to support diagnosis of Left Ventricular Systolic Dysfunction (LVSD). AiTiALVSD is intended to assess LVSD, defined as a Left Ventricular Ejection Fraction (LVEF) less than or equal to 40%, in adults at risk for heart failure using 12-lead ECG data.

AiTIALVSD is meant for use in professional medical facilities by qualified clinicians. The software is indicated for use on adults only.

When the results (High or Low) from AiTiALVSD are applied in a clinical setting to an individual patient's ECG data, they can assist in clinical decision-making regarding patient diagnosis. However, these results should be used in conjunction with other clinical data and should not be the sole determinant for a clinical diagnosis.

The target population includes adults at risk for heart failure. This population includes, but is not limited to, individuals with coronary artery disease, diabetes mellitus, cardiomyopathies, hypertension, obesity; history of myocardial infarction; aortic stenosis; atrial fibrillation; exposure to cardiotoxic pharmaceutical therapies; cardiac hypertrophy evident in chest X-rays; and postpartum women.

Additionally, AiTiALVSD should not be used on ECGs with a paced rhythm.

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.

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510(k) Summary

AiTiALVSD

Sponsor Name: Medical AI Co., Ltd.
13th Floor, 38, Yeongdong-daero 85-gil, Gangnam-gu, Seoul 06180 Republic of Korea
Phone: +82 (0)2 2058 0521

Contact: Hye-ri Choi
QRA Leader, Regulatory Affairs
Medical AI Co., Ltd.
lini.choi@medicalai.com

Primary Correspondent: Suzanne Goodman
VP Q&R US, Regulatory Affairs
Medical AI, Inc.
suzanne.g@medicalai-global.com

Date Summary Prepared: September 29, 2026

Device Trade Name: AiTiALVSD

Common Name ECG Analysis software

Classification Name: Cardiovascular machine learning-based notification software

Regulation Number: 21 CFR § 870.2380

Product Code: QYE
Predicate Device: Anumana, Inc. Low Ejection Fraction AI-ECG Algorithm
Submission Number: K250652
Product Code: QYE

Indications For Use

AiTiALVSD is a software that utilizes artificial intelligence (AI) algorithms to support diagnosis of Left Ventricular Systolic Dysfunction (LVSD). AiTiALVSD is intended to assess LVSD, defined as a Left Ventricular Ejection Fraction (LVEF) less than or equal to 40%, in adults at risk for heart failure using 12-lead ECG data.

AiTiALVSD is meant for use in professional medical facilities by qualified clinicians. The software is indicated for use on adults only.

When the results (High or Low) from AiTiALVSD are applied in a clinical setting to an individual patient's ECG data, they can assist in clinical decision-making regarding patient diagnosis. However, these results should be used in conjunction with other clinical data and should not be the sole determinant for a clinical diagnosis.

The target population includes adults at risk for heart failure. This population includes, but is not limited to, individuals with coronary artery disease, diabetes mellitus, cardiomyopathies, hypertension, obesity; history of myocardial infarction; aortic stenosis; atrial fibrillation; exposure to cardiotoxic pharmaceutical therapies; cardiac hypertrophy evident in chest X-rays; and postpartum women.

Additionally, AiTiALVSD should not be used on ECGs with a paced rhythm.

Warnings

- A. Users should not rely solely on the device output - including the absence or presence of a suspected finding—to determine patient management or the need for follow-up. Final interpretation and clinical decision-making must be performed by a qualified clinician.
- B. The output should be interpreted only in conjunction with a clinician's professional judgment and patient's full clinical evaluation. AiTiALVSD results are not a diagnosis and must not be used as a substitute for echocardiography or other clinical diagnostic tests.

Device Description

The electrocardiogram (ECG) analysis software, AiTiALVSD allows users to view the analysis results of an artificial intelligence algorithm predicting the likelihood of Left Ventricular Systolic Dysfunction (LVSD) based on ECG data. The data can be automatically transmitted from an ECG medical device or uploaded by the user. The user is required to upload the input ECG data in XML format. The results and associated ECG data can be saved in HL7 aECG format XML, JPG, or DICOM format.

AiTiALVSD analyzes only 12-lead ECG data and provides a binary output of High or Low for interpretation by a qualified clinician. The output indicates a high or low likelihood of Left Ventricular Systolic Dysfunction, defined as a left ventricular ejection fraction (LVEF) $\leq 40\%$ by echocardiography. The result must be interpreted in conjunction with other clinical information and is not a standalone diagnosis.

Intended Use and Technological Characteristics Comparison

The intended use of the subject and predicate devices is the same. Both are intended for analysis of 12-lead resting ECG recordings using machine-learning techniques to detect signs of cardiovascular conditions for further referral or diagnostic follow-up. The indications for use of the subject and predicate devices are similar; differences in the indications for use statement do not result in a new intended use.

The subject device has similar technological characteristics as the predicate device. Both are machine-learning based software used to analyze recordings of resting 12-lead ECGs. Differences do not raise different questions of safety or effectiveness.

Summary of Non-Clinical Studies

The performance of AiTiALVSD was evaluated based on non-clinical testing, as follows:

- Software Verification and Validation (V&V): SW V&V activities were completed and all Unit Tests, Integration Tests, System Tests, and Design Inspection cases met acceptance criteria. There were no anomalies during testing.
- Cybersecurity Testing: Cybersecurity activities were completed and associated risks have been appropriately mitigated.
- Human Factors Assessment: No potential use errors were identified during analysis of FDA databases, and the completed usability assessment supports the conclusion that use-related risks have been appropriately mitigated.

Summary of Model Training and Clinical Validation Performance-Testing

The training dataset comprised approximately 148,624 patients contributing 400,339 ECGs collected across 16 hospitals in Korea. Each dataset included paired ECGs and TTE of left ventricular ejection fraction (LVEF), ensuring accurate labeling for model training. This dataset was used to train a deep learning neural network with transformer-based self-attention mechanisms via supervised learning.

The model was trained to identify patients with LVSD (LVEF $\leq 40\%$) based solely on ECG data.

Demographic characteristics of the training dataset are described in Table 1.

The performance of AiTiALVSD in identifying patients with LVSD as determined by echocardiogram

was evaluated in a US retrospective study. This study utilized a real-world dataset of patients from geographically distinct sites with a range of clinically used ECG machines. Multiple models of 12-lead ECG machines were included in the study to provide ECG inputs to the AiTiALVSD software. No data present in the training dataset was used in the performance study.

In the performance study, AiTiALVSD was applied to patients meeting inclusion/exclusion criteria and who received a 12-lead ECG, comprehensively capturing the intended use population. All patients in the performance study had a clinically acquired ECG and were aged 18 years or greater at the time of the ECG. Demographic characteristics of the training data and performance study data are described in Table 1. The LVSD status of each patient was determined by echocardiogram. Results of "High Risk for LVSD" or "Low Risk for LVSD" were generated by AiTiALVSD and compared to the reference LVEF status to establish device performance.

Table 1. Demographic and Clinical Characteristics of the Training Datasets and Performance Study Dataset

Parameter	Performance Study ¹	Training Dataset
N (patients)	22,101	148,624
ECG samples	22,101	400,339
Age (in years) Mean (SD) Median (IQR) Min/Max	65 (16) 67 (56, 77) 18, 106	63.17 (15.14)
Age, n (%)	<40 1,942 (8.8%) 40–49 1,844 (8.3%) 50–59 3,173 (14%) 60–69 5,308 (24%) 70–79 5,384 (24%) ≥80 4,450 (20%)	18–105
Sex (%) Female Male	10,991 (50%) 11,110 (50%)	45% 55%
Race (%) White Black or African American Asian American Indian or Alaska Native Native Hawaiian or Other Pacific Islander Other / Unknown Missing information	16,507 (78%) 2,026 (9.6%) 935 (4.4%) 422 (2.0%) 44 (0.2%) 1,180 (5.6%) 987	Not collected
Ethnicity (%) Hispanic or Latino Not Hispanic or Latino Unknown/missing	2,478 (11%) 19,247 (89%) 376	Not collected
BMI (%) Mean Median	29 (8) 29 (24, 35)	Not collected
Clinical Characteristics (%) Hypertension Diabetes Mellitus Coronary Artery Disease Myocardial Infarction Atrial fibrillation Congestive Heart Failure Chronic Kidney Disease	14,337 (65%) 6,602 (30%) 8,939 (40%) 3,840 (17%) 5,797 (26%) 6,309 (29%) 4,936 (22%)	Not collected

¹ Intent-to-Diagnose (ITD) Set. Based on all ECG acquisition devices tested in the clinical study; paced rhythms excluded

The clinical validation study included a limited number of Black or African American subjects (2,026, 9.6% of subjects with recorded race) and was not powered to establish performance in this population separately. In this subgroup, the specificity was lower than in the overall study population.

Based on the results of the US clinical study, the PPV and NPV values can be calculated based on the following prevalences.

<u>LVSD prevalence</u>	<u>PPV</u>	<u>NPV</u>
<u>6%</u>	<u>0.219</u>	<u>0.987</u>
<u>8%</u>	<u>0.277</u>	<u>0.983</u>
<u>10%</u>	<u>0.328</u>	<u>0.978</u>
<u>10.5% (Observed in the US clinical study)</u>	<u>0.340</u>	<u>0.977</u>
<u>12%</u>	<u>0.375</u>	<u>0.973</u>
<u>14%</u>	<u>0.417</u>	<u>0.968</u>
<u>16%</u>	<u>0.456</u>	<u>0.963</u>
<u>18%</u>	<u>0.491</u>	<u>0.958</u>
<u>20%</u>	<u>0.524</u>	<u>0.952</u>

Substantial Equivalence Conclusion

Based on non-clinical and clinical performance testing conducted, the subject device, AiTiALVSD, is substantially equivalent to the predicate device from Anumana, Inc. (K250652). The devices have the same intended use, any differences in technological characteristics do not raise different questions of safety and effectiveness, and the results of non-clinical testing and clinical performance validation demonstrate that the subject device's performance is substantially equivalent to the predicate device's performance.

Table 2. Substantial Equivalence Comparison

	Subject Device	Predicate Device	Comparison
Product Name	AiTIALVSD	ECG-AI Low Ejection Fraction (LEF) 12-Lead Algorithm	
510(k)	K254302	K250652	
Manufacturer	Medical AI Co., Ltd.	Anumana, Inc.	
Intended Use	Analysis of 12-lead electrocardiograms (ECGs) using machine-learning techniques to detect signs of cardiovascular conditions for further referral or diagnostic follow-up.	Analysis of 12-lead electrocardiograms (ECGs) using machine-learning techniques to detect signs of cardiovascular conditions for further referral or diagnostic follow-up.	Same
Rx / OTC	Rx only	Rx only	Same
Cardiovascular Condition Evaluated	Left Ventricular Ejection Fraction $\leq 40\%$	Left Ventricular Ejection Fraction $\leq 40\%$	Same
Age of Intended Patient	Adults	Adults	Same
Machine-Learning based Model	Locked	Locked	Same
Input	12-lead ECG waveform in digital format	12-lead ECG waveform in digital format	Same
Output	For each ECG, the output is presented as one of the following: “Low-risk group for Left Ventricular Systolic Dysfunction,” “High-risk group for Left Ventricular Systolic Dysfunction”, or “Error”.	Detection of LVEF (Left Ventricular Ejection Fraction less than or equal to 40%) from an ECG signal	Same - Both suggest the likelihood of a cardiovascular disease or condition
Clinical Performance	Sensitivity ¹ 83.7 (82.1–85.2) Specificity ¹ 81.0 (80.4–81.5) PPV ¹ 34.5 (33.3–35.8) NPV ¹ 97.7 (97.5–97.9)	Sensitivity 84.5% (82.2%, 86.6%) Specificity 83.6% (82.9%, 84.2%) PPV 30.5% (28.8%, 32.1%) NPV 98.4% (98.2%, 98.7%)	Similar – differences are not clinically significant
Data Display	The algorithm output is provided through AiTiALVSD’s user interface and, if integrated, to third-party software systems.	Algorithm output is provided to third party software that displays the result to clinicians. Output provided for each ECG is “Low LVEF Detected”, “Low LVEF Not Detected” or “Error”).	Similar – Both devices provide data suggesting the likelihood of a cardiovascular disease or condition for further referral or diagnostic follow-up.
Hardware	Compatible 12-Lead diagnostic ECG machines with 500Hz digital output	Compatible 12-Lead diagnostic ECG machines with 500Hz digital output	Same
Software	Medical AI proprietary algorithm and application	Anumana proprietary algorithm and application	Similar – The devices incorporate their own proprietary

	Subject Device	Predicate Device	Comparison
Product Name	AiTiALVSD	ECG-AI Low Ejection Fraction (LEF) 12-Lead Algorithm	
			algorithms and applications.

¹ Intent-to-Diagnose (ITD) Set. Based on all ECG acquisition devices tested in the clinical study; paced rhythms excluded, at observed prevalence of 10.5%.