



September 25, 2026

Tempus AI, Inc.
Bethany Barrett
Director, Regulatory Affairs
600 W Chicago Ave. Suite #510
Chicago, Illinois 60654

Re: K254297
Trade/Device Name: Tempus ECG-MR
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular Machine Learning-Based Notification Software
Regulatory Class: Class II
Product Code: SIJ
Dated: August 26, 2026
Received: August 26, 2026

Dear Bethany Barrett:

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. FDA's substantial equivalence determination

also included the review and clearance of your Predetermined Change Control Plan (PCCP), PLN-000503 ECG-MR Predetermined Change Control Plan. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively. 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)

K254297

Device Name

Tempus ECG-MR

Indications for Use (Describe)

Tempus ECG-MR is software intended to analyze resting, non-ambulatory 12-lead ECG recordings and detect signs associated with having moderate or severe mitral regurgitation (MR). It is for use on clinical diagnostic ECG recordings collected at a healthcare facility from patients:

- 65 years of age or older
- At risk of cardiovascular disease. Such cardiovascular risk factors include, but are not limited to, history of coronary artery disease, hypertension, obesity, or diabetes; or other signs or symptoms of heart disease, such as dyspnea, chest pain, or lower extremity edema.
- Without prior mitral valve intervention
- Without prior diagnosis of moderate or severe mitral regurgitation

Tempus ECG-MR only analyzes ECG data and provides a binary output for interpretation. Tempus ECG-MR is not intended to be a stand-alone diagnostic tool for cardiac conditions, should not be used for serial patient monitoring, and should not be used on ECGs with paced rhythms. Results should be interpreted in conjunction with other diagnostic information, including the patient's original ECG recordings and other tests, as well as the patient's symptoms and clinical history.

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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"TEMPUS

510(k) Summary Tempus ECG-MR

Sponsor Name:	Tempus AI, Inc. 600 W Chicago Ave Ste #510, Chicago, IL 60654 Phone: (833) 514-4187
Contact Person:	Bethany Barrett Director, Regulatory Affairs Tempus AI, Inc. Phone: (800) 739-4137 bethany.barrett@tempus.com
Date Summary Prepared:	September 24, 2026
Device Trade Name:	Tempus ECG-MR
Common Name:	AI-based ECG analysis software
Classification Name:	Cardiovascular machine learning-based notification software
Regulation Number:	21 CFR § 870.2380
Product Code:	SIJ
Predicate Device:	Anumana ECG-AI Pulmonary Hypertension 12-Lead algorithm
Submission Number:	K252360
Product Code:	SAT

Indications For Use

Tempus ECG-MR is software intended to analyze resting, non-ambulatory 12-lead ECG recordings and detect signs associated with having moderate or severe mitral regurgitation (MR). It is for use on clinical diagnostic ECG recordings collected at a healthcare facility from patients:

- 65 years of age or older
- At risk of cardiovascular disease. Such cardiovascular risk factors include, but are not limited to, history of coronary artery disease, hypertension, obesity, or diabetes; or other signs or symptoms of heart disease, such as dyspnea, chest pain, or lower extremity edema.
- Without prior mitral valve intervention
- Without prior diagnosis of moderate or severe mitral regurgitation

Tempus ECG-MR only analyzes ECG data and provides a binary output for interpretation. Tempus ECG-MR is not intended to be a stand-alone diagnostic tool for cardiac conditions, should not be used for serial patient monitoring, and should not be used on ECGs with paced rhythms. Results should be interpreted in conjunction with other diagnostic information, including the patient's original ECG recordings and other tests, as well as the patient's symptoms and clinical history.

General Warnings and Precautions

- Tempus ECG-MR has not been evaluated in and should not be used for patients younger than 65 years of age.
- Tempus ECG-MR is not intended to replace other diagnostic tests.
- Results do not represent a diagnosis of mitral regurgitation.
- Results do not rule-out mitral regurgitation.
- Tempus ECG-MR should not be used on ECG recordings with paced rhythms.
- Tempus ECG-MR should not be used for serial patient monitoring. Serial testing for the same patient has not been validated.
- Tempus ECG-MR should not be used to initiate any therapy or treatment for MR.
- Tempus ECG-MR should not be used for repeated testing of the same patient within a 12 month period.

Device Description

Tempus ECG-MR is a cardiovascular machine learning software intended for analysis of 12-lead resting ECG recordings using machine-learning techniques to detect signs associated with cardiovascular conditions for further referral or diagnostic follow-up. The software employs machine learning techniques to analyze ECG recordings and detect signs associated with a patient experiencing moderate or severe mitral regurgitation (MR). The device is designed to extract otherwise unavailable information from ECGs conducted under the standard of care, to help health care providers better identify patients who may be at risk for undiagnosed MR in order to evaluate them for further referral or diagnostic follow up.

As input, the software takes data from a patient's 12-lead resting ECG (including age and sex). It is only compatible with ECG recordings collected using 'wet' Ag/AgCl electrodes with conductive gel/paste, and using compatible ECG machine models. It checks the format and quality of the input data, analyzes the data via a trained and 'locked' machine-learning model to generate an uncalibrated risk score, converts the risk score to a binary output (or reports that the input data are unclassifiable), and outputs results. Uncalibrated risk scores at or above the threshold are returned as 'Mitral Regurgitation Detected,' and uncalibrated risk scores below the threshold are returned as 'Mitral Regurgitation Not Detected.' This information is used to support clinical decision making regarding the need for further referral or diagnostic follow-up. Results should not be used to direct any therapy against MR itself. Tempus ECG-MR is not intended to replace other diagnostic tests.

Tempus ECG-MR does not have a dedicated user interface (UI). Input data comprising ECG tracings, tracing metadata (e.g., sample count, sample rate, patient age/sex), is provided to Tempus ECG-MR through standard communication protocols (e.g., file exchange) with other medical systems (e.g., electronic health record systems, hospital information systems, or other data display, transfer, storage, or format-conversion software). Results from Tempus ECG-MR are returned to users in an equivalent manner.

Intended Use and Technological Characteristics Comparison

Both the subject device and the predicate device are intended for analysis of ECG recordings using machine-learning techniques to detect signs of cardiovascular conditions. The indications for use of the subject and predicate devices are similar; differences in the indications for use statements 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 (e.g., in the proprietary AI algorithm and the disease that is being detected) do not raise different questions of safety or effectiveness.

Summary of Non-Clinical Studies

The performance of Tempus ECG-MR 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.
- 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 Clinical Studies

Clinical performance of Tempus ECG-MR for analysis of ECG tracings to identify signs associated with a clinical diagnosis of mitral regurgitation (MR), was validated in a retrospective observational cohort study, in which the device was used as intended in a representative intended use population. The model was trained on data from more than 720,000 ECGs. The average age of patients in the training dataset was 65 years. 48% of subjects were female and 52% were male. The racial distribution of the patients in the training dataset was 96% White, and 2% Black, and 2% Asian/Other/Unknown.

The model was locked prior to clinical performance validation on an independent real-world dataset derived from 4 geographically distinct US clinical sites. Each clinical site contributed >1,500 patient records. The total study size was greater than 6,300 ECGs. The median age of study participants was 76 years. 53% of subjects were female and 48% were male. The racial distribution of the study population was 82% White, 12% Black, 2% Asian, and 4% Other/Unknown.

The point estimate for sensitivity for the detection of moderate or severe MR was 75% and the lower bound of the 95% CI was 70% which was above the predetermined acceptance criteria of 65%. The point estimate for specificity was 70% and the lower bound of the 95% CI was 69% which was above the predetermined acceptance criteria of 65%. No clinically significant differences in performance were observed based on analysis of subgroups.

Based on the 6.0% prevalence of moderate or severe MR observed in the clinical performance study, the overall positive predictive value (PPV) was 13.9% and the negative predictive value (NPV) was 97.8%. Other literature-based estimates of moderate or severe MR prevalence in the age 65+ population have been documented between 3.5% to 7.3%, noting that the range can likely be attributed to differences in study recruitment setting and patient symptom and risk-factor status. Table 1 estimates Tempus ECG-MR PPV and NPV for various prevalence values.

Demographic characteristics of the performance study data and training data are described in Table 2.

Table 1. Tempus ECG-MR PPV and NPV by Prevalence

Prevalence	PPV	NPV
2.0%	4.9%	99.3%
3.0%	7.3%	98.9%
4.0%	9.5%	98.5%
5.0%	11.7%	98.2%
6.0% (ECG-MR performance study observed value)	13.9%	97.8%
7.0%	16.0%	97.4%
8.0%	18.0%	97.0%
9.0%	20.0%	96.6%

Table 2. Clinical Performance Validation Study and Training Dataset Demographic Characteristics

Parameter	Performance Study	Training Dataset
N (ECGs)	6,341	724,130
Age (in years) Mean (SD) Median Q1/Q3 Min/Max	76 (7) 76 70/82 65/90	65 (15) 66 55 / 76 18 / 90
Age (%) [18, 65) [65, 75) ≥75	N/A 2,991 (47) 3,350 (53)	335,246 (47) 190,813 (26) 198,071 (27)
Sex (%) Male Female Unknown	3,015 (48) 3,326 (53) N/A	375,426 (52) 348,434 (48) 270 (<1)
Race (%) White Black Asian Other Unknown	5,206 (82) 728 (12) 148 (2) 128 (2) 131 (2)	696,898 (96) 15,577 (2) 3,942 (1) 5,011 (1) 2,702 (<1)

Parameter	Performance Study	Training Dataset
Ethnicity (%)		
Hispanic	455 (7)	14,502 (2)
Not Hispanic	5,653 (89)	649,103 (90)
Unknown	233 (4)	60,525 (8)
BMI (n (%))		
<25	1,332 (21)	146,107 (20)
[25, 30)	1,621 (26)	194,486 (27)
≥30	3,136 (50)	318,477 (44)
Unknown	252 (4)	65,060 (9)

Substantial Equivalence Conclusion

Based on non-clinical and clinical performance testing conducted, the subject device, Tempus ECG-MR, is substantially equivalent to the predicate device, Anumana ECG-AI PH 12-Lead Algorithm (K252360). 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 is substantially equivalent to the predicate device.

Table 3. Substantial Equivalence Comparison

	Subject Device (Tempus ECG-MR)	Predicate Device (Anumana ECG-AI PH 12-Lead Algorithm, K252360)
Intended Use	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 ECG-AI PH 12-Lead algorithm is software intended to aid in earlier detection of elevated mean pulmonary arterial pressure (mPAP), an indicator of pulmonary hypertension, in adults presenting with dyspnea.
Rx / OTC	Rx only	Same
Cardiovascular Condition Evaluated	Mitral Regurgitation (MR) of moderate or greater severity.	Same
Age of Intended Patient (Years)	65+	Adult (age 22+)
Machine-Learning based Model	Locked	Same
Input	12-lead ECG tracing, patient age, patient sex	Same

	Subject Device (Tempus ECG-MR)	Predicate Device (Anumana ECG-AI PH 12-Lead Algorithm, K252360)
Output	Detection of signs associated with MR is provided as "Mitral Regurgitation Detected", "Mitral Regurgitation Not Detected" or "Unclassifiable" to medical information systems for display to clinicians.	Algorithm output is provided to third party software that displays a binary result to clinicians. Output provided for each ECG is "Detected," "Not Detected" or "Error".
Data Display	Output is provided to third party software for display of results.	Same
Hardware	Tempus ECG-MR is a software-only device. It analyzes ECGs from compatible 12-Lead diagnostic ECG machines with 500Hz digital output.	Same
Software	Proprietary algorithm and software	Same

Predetermined Change Control Plan (PCCP)

A Predetermined Change Control Plan (PCCP) has been established for the Tempus ECG-MR device, which permits the following changes:

- Retraining of the Machine Learning Device Software Functions (ML-DSF) on the original training data combined with new data to improve performance.
- Updates to the device software to support analysis of ECGs from additional ECG machine models.

The PCCP does not include provisions for implementation of adaptive algorithms that will continuously learn in the field. Updates to the Tempus ECG-MR ML-DSF will be trained, tuned, and locked prior to release of the software to the field. A procedure has also been established for updating the device labeling in order to inform users about the changes implemented under this FDA-authorized PCCP, including any updates in device performance and compatibility with ECG machine models.

The PCCP specifies verification and validation activities in place to implement the changes in a controlled manner such that the modified device remains as safe and effective as the predicate device. Such activities include clinical validation methods and ground truth abstraction based on the same clinical study protocol used for the cleared device, detailed practices for sequestration of validation test data, clinical validation acceptance criteria based on performance of the cleared device, software verification testing per the protocol established for the cleared device, and ongoing cybersecurity monitoring practices.

Parameter	Performance Study	Training Dataset
Black Asian Other Unknown	728 (12) 148 (2) 128 (2) 131 (2)	15,577 (2) 3,942 (1) 5,011 (1) 2,702 (<1)
Ethnicity (%) Hispanic Not Hispanic Unknown	455 (7) 5,653 (89) 233 (4)	14,502 (2) 649,103 (90) 60,525 (8)
BMI (n (%)) <25 [25, 30) ≥30 Unknown	1,332 (21) 1,621 (26) 3,136 (50) 252 (4)	146,107 (20) 194,486 (27) 318,477 (44) 65,060 (9)

Substantial Equivalence Conclusion

Based on non-clinical and clinical performance testing conducted, the subject device, Tempus ECG-MR, is substantially equivalent to the predicate device, Anumana ECG-AI PH 12-Lead Algorithm (K252360). 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 is substantially equivalent to the predicate device.

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Rx / OTC	Rx only	Same
Cardiovascular Condition Evaluated	Mitral Regurgitation (MR) of moderate or greater severity.	Same
Age of Intended Patient (Years)	65+	Adult (age 22+)