August 21, 2026

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

Re: K253699
Trade/Device Name: Tempus ECG-PH
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular Machine Learning-Based Notification Software
Regulatory Class: Class II
Product Code: SAT
Dated: July 24, 2026
Received: July 24, 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). 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,

Jackson Hair -S

for

LCDR 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

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.

510(k) Number *(if known)*
K253699

Device Name
Tempus ECG-PH

Indications for Use *(Describe)*
Tempus ECG-PH is software intended to analyze resting, non-ambulatory 12-lead ECG recordings and detect signs associated with a patient having elevated mean pulmonary artery pressure (mPAP > 20 mmHg), an indicator of pulmonary hypertension (PH). It is for use on clinical diagnostic 12-lead ECG recordings collected at a healthcare facility from patients:

- 40 years of age or older
- with cardiovascular symptoms (dyspnea, fatigue, chest pain, or edema)
- who do not have a known history of PH

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

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.
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Date Summary Prepared: August 20, 2026
Device Trade Name: Tempus ECG-PH
Common Name: AI-based ECG analysis software
Classification Name: Cardiovascular machine learning-based notification software
Regulation Number: 21 CFR § 870.2380
Product Code: SAT

Predicate Device: CorVista System with PH Add-On
Submission Number: K233666
Product Code: SAT

Indications For Use

Tempus ECG-PH is software intended to analyze resting, non-ambulatory 12-lead ECG recordings and detect signs associated with a patient having elevated mean pulmonary artery pressure (mPAP > 20 mmHg), an indicator of pulmonary hypertension (PH). It is for use on clinical diagnostic 12-lead ECG recordings collected at a healthcare facility from patients:

- 40 years of age or older
- with cardiovascular symptoms (dyspnea, fatigue, chest pain, or edema)
- who do not have a known history of PH

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

General Warnings and Precautions

- Tempus ECG-PH has not been evaluated in and should not be used for patients younger than 40 years of age.
- Tempus ECG-PH should not be used on ECG recordings with paced rhythms.
- Tempus ECG-PH is not intended to replace other diagnostic tests.

- Results do not represent a diagnosis of pulmonary hypertension.
- Results do not rule-out pulmonary hypertension.
- Tempus ECG-PH should not be used to initiate any therapy or treatment for pulmonary hypertension.
- Invasive follow-up testing such as right heart catheterization (RHC) should not be performed based solely on Tempus ECG-PH results.
- Tempus ECG-PH should not be used for serial patient monitoring. Serial testing for the same patient has not been validated.
- Tempus ECG-PH should not be used for repeated testing of the same patient within a 12 month period.

Device Description

Tempus ECG-PH 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 elevated mean pulmonary artery pressure, an indicator of pulmonary hypertension (PH). 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 PH 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 'Elevated PH Risk Detected,' and uncalibrated risk scores below the threshold are returned as 'Elevated PH Risk 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 PH itself. Tempus ECG-PH is not intended to replace other diagnostic tests.

Tempus ECG-PH 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-PH 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-PH are returned to users in an equivalent manner.

Input Data Requirements

The device requires data and metadata from a 10-second 12-lead resting electrocardiogram recording, including:

- Lead trace data from the input ECG including Lead I, Lead II, Lead V1, Lead V2, Lead V3, Lead V4, Lead V5, Lead V6, as base64 encoded strings of signed 16-bit integer arrays with complete voltage-time traces of 10 seconds
- Sample rate in Hz as a string that equals "500"
- Sample count as a string that equals "5000"
- Lead least significant bit as a string representing microvolts per bit, greater than 0μV and less than or equal to 5μV
- Acceptable values of a high-pass filter between 0.05 Hz and .67 Hz
- Acceptable values of a low-pass filter between 40 Hz and 150 Hz
- Patient sex as a string of "male" or "female"
- Patient age in unit values of years, months, weeks, days, or hours, or date of birth and recording acquisition date, with a value greater than or equal to 40 years
- Compatible ECG machine manufacturer and model

- Last ECG acquisition date for which the patient received a Tempus ECG-PH prediction. Null if the patient has not received a PH prediction.

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, with only minor differences. Mainly, the Tempus ECG-PH is a software-only device and does not include or require dedicated hardware for ECG acquisition, while the CorVista system requires use of the provided seven-channel lead set. Both devices 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 Tempus ECG-PH 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 Clinical Studies

Clinical performance of Tempus ECG-PH for analysis of ECG tracings to identify signs associated with a clinical diagnosis of an elevated mPAP, an indicator of PH, 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 530,000 ECGs. The average age of patients in the training dataset was 65 years. 49% of subjects were female and 51% 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 3 geographically distinct US clinical sites. Each clinical site contributed >340 patient records. The total study size was greater than 1,000 ECGs. The median age of study participants in the combined (RHC and Echo) populations was 69 years. 53% of subjects were female and 47% were male. The racial distribution of the study population was 74% White, 18% Black, 4% Asian, and 4% Other/Unknown.

Patients with pulmonary hypertension were identified by the presence of an elevated mPAP on RHC or an elevated tricuspid regurgitation velocity (TRV) on echocardiogram. Patients without pulmonary hypertension were identified by an echocardiogram that showed a low likelihood of PH (TRV ≤ 2.8 m/sec or null, normal LV systolic and diastolic function and no echo evidence of PH) or a normal mPAP on RHC. Results of “Elevated PH Risk Detected” or “Elevated PH Risk Not Detected” were generated by Tempus ECG-PH and compared to the pulmonary hypertension ground truth status to establish device performance.

In the combined populations (RHC and echo), Tempus ECG-PH demonstrated a sensitivity of 87.9% for the detection of PH (mPAP ≥25 mmHg or TRV >3.4 m/sec) and the lower bound of the 95% CI was 85.1% which was above the predetermined acceptance criteria of 70%. The specificity (negative percent agreement) for detection of PH negative (mPAP ≤ 20 mmHg or echo with low likelihood of PH) was 71.5% and the lower bound of the 95% CI was 65.6% which was above the predetermined acceptance criteria of 60%. The overall positive predictive value (PPV) observed in the study (for a RHC sensitivity cutoff of RHC mPAP ≥ 25) was 15.5% and the negative predictive value (NPV) was 99.0%. An assumed PH prevalence of 5.6% was used to calculate PPV and NPV in the intended use population based on an estimate from multiple large institutional datasets. No clinically significant differences in performance were observed based on analysis of subgroups. Performance was also analyzed in PH screen type subpopulations (RHC-only and echo-only) as presented in Table 2, and demographic subgroups as presented in Table 3.

Demographic characteristics of the training data and performance study data are described in Table 1.

Table 1. Clinical Performance Validation Study and Training Dataset Demographic Characteristics

Parameter	Training Dataset	Performance Study: Combined (RHC and Echo) Populations
N (ECGs)	532,528	1016
Age (years)		
Mean (SD)	65 (15)	68 (12)
Median	67	69
Q1 / Q3	57 / 76	59 / 77
Min / Max	18 / 90	40 / 90
Age (%)		
18 to 40	33,610 (6)	0
40 to 64	202,065 (38)	407 (40)
65+	296,853 (56)	609 (60)
Sex (%)		
Female	262,928 (49)	538 (53)
Male	269,475 (51)	478 (47)
Unknown	125 (<1)	0
Race (%)		
Asian	3,660 (1)	38 (4)
Black	12,495 (2)	181 (18)
White	510,750 (96)	755 (74)
Other	3,685 (1)	29 (3)
Unknown	1,938 (<1)	13 (1)
Ethnicity (%)		
Hispanic	11,166 (2)	87 (9)
Not Hispanic	490,964 (92)	929 (91)
Unknown	30,398 (6)	0
BMI (%)		
< 25	116,399 (22)	202 (20)

Parameter	Training Dataset	Performance Study: Combined (RHC and Echo) Populations
25 to 29 ≥ 30 Unknown	151,236 (28) 216,780 (41) 48,113 (9)	241 (24) 572 (56) 1 (<1)

Table 2. Tempus ECG-PH Results Summary - Overall Combined (RHC and Echo), Echo-Only, and RHC-Only Populations

	Sensitivity (95% CI)		Specificity (95% CI)	PPV / NPV (based on prevalence of 5.6%)	
Echo and RHC Thresholds	TRV >3.4 m/sec RHC mPAP ≥ 25 mmHg	TRV >3.4 m/sec RHC mPAP > 20 mmHg	TRV ≤ 2.8 m/sec or null RHC mPAP ≤ 20 mmHg	Sensitivity: TRV >3.4 m/sec RHC mPAP ≥ 25 mmHg Specificity: TRV ≤ 2.8 m/sec or null RHC mPAP ≤ 20 mmHg	Sensitivity: TRV >3.4 m/sec RHC mPAP > 20 mmHg Specificity: TRV ≤ 2.8 m/sec or null RHC mPAP ≤ 20 mmHg
Overall Combined Performance (RHC and Echo)	87.9% (85.1%, 90.3%)	82.7% (79.8%, 85.3%)	71.5% (65.6%, 76.9%)	15.5% / 99.0%	14.7% / 98.6%
Subgroup Analyses by PH Screen Type					
Echo-Only	96.8% (92.1%, 99.1%)		72.9% (66.4%, 78.7%)	17.5% / 99.7%	
RHC-Only	85.6% (82.2%, 88.6%)	79.8% (76.5%, 82.9%)	65.2% (49.8%, 78.6%)	12.7% / 98.7%	12.0% / 98.2%

Table 3. Tempus ECG-PH Subgroup Results Summary - Overall Combined (RHC and Echo)

	Sensitivity (95% CI) (n/N)		Specificity (95% CI) (n/N)
Subgroup	mPAP≥25 mmHg or TRV > 3.4 m/sec	mPAP>20 mmHg or TRV > 3.4 m/sec	mPAP ≤ 20 mmHg or TRV ≤ 2.8 m/sec (or null)
Age			
[40-65)	91.0% (86.4%, 94.4%) (202/222)	86.2% (81.3%, 90.1%) (224/260)	73.5% (65.6%, 80.4%) (108/147)
≥ 65	86.2% (82.4%, 89.4%) (349/405)	80.8% (77.1%, 84.2%) (401/496)	69.0% (59.6%, 77.4%) (78/113)
Sex			
Female	87.8% (83.9%, 91.1%) (296/337)	84.2% (80.2%, 87.7%) (330/392)	73.3% (65.3%, 80.3%) (107/146)
Male	87.9% (83.6%, 91.4%) (255/290)	81.0% (76.6%, 84.9%) (295/364)	69.3% (60.0%, 77.6%) (79/114)
Race			
White	87.4% (84.1%, 90.3%) (418/478)	82.2% (78.8%, 85.2%) (479/583)	69.8% (62.3%, 76.5%) (120/172)
Black	90.1% (83.3%, 94.8%) (109/121)	84.9% (77.8%, 90.4%) (118/139)	66.7% (50.5%, 80.4%) (28/42)
Asian	83.3% (51.6%, 97.9%) (10/12)	76.9% (46.2%, 95.0%) (10/13)	92.0% (74.0%, 99.0%) (23/25)
Other	90.0% (55.5%, 99.7%) (9/10)	84.6% (54.6%, 98.1%) (11/13)	68.8% (41.3%, 89.0%) (11/16)
Unknown	83.3% (35.9%, 99.7%) (5/6)	87.5% (47.3%, 99.7%) (7/8)	80.0% (28.4%, 99.5%) (4/5)
Ethnicity			
Hispanic	88.2% (72.5%, 96.7%) (30/34)	79.1% (64.0%, 90.0%) (34/43)	77.3% (62.2%, 88.5%) (34/44)
Not Hispanic	87.9% (85.0%, 90.4%) (521/593)	82.9% (79.9%, 85.6%) (591/713)	70.4% (63.8%, 76.4%) (152/216)
Race/Ethnicity			
White non-Hispanic	87.1% (83.7%, 90.0%) (399/458)	82.3% (78.8%, 85.3%) (459/558)	68.0% (59.9%, 75.4%) (102/150)
Other	89.9% (84.4%, 94.0%) (152/169)	83.8% (78.0%, 88.7%) (166/198)	76.4% (67.3%, 83.9%) (84/110)
BMI			
< 25	96.6% (91.5%, 99.1%) (114/118)	92.2% (86.5%, 96.0%) (130/141)	70.5% (57.4%, 81.5%) (43/61)
[25, 30)	88.8% (81.9%, 93.7%) (111/125)	80.4% (73.3%, 86.3%) (127/158)	77.1% (66.6%, 85.6%) (64/83)
≥ 30	84.9% (80.9%, 88.3%) (325/383)	80.5% (76.5%, 84.0%) (367/456)	68.1% (58.8%, 76.4%) (79/116)

Note: One patient with unknown BMI was excluded from the table above.

Substantial Equivalence Conclusion

Based on non-clinical and clinical performance testing conducted, the subject device, Tempus ECG-PH, is substantially equivalent to the predicate device, CorVista System with PH Add-On (K233666). 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. The Anumana ECG-AI Pulmonary Hypertension 12-Lead algorithm (K252360) was used as a reference device relative to technological characteristics (software-only device with 12-lead ECG input).

Table 4. Substantial Equivalence Comparison

	Subject Device (Tempus ECG-PH)	**Predicate Device (CorVista System with PH Add-On, K233666)**	**Reference 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 CorVista System is intended to non-invasively analyze physiological signals using machine learning techniques to indicate the likelihood of a cardiovascular disease or condition.	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	Same
Cardiovascular Condition Evaluated	Risk of a patient having elevated mean pulmonary arterial pressure (mPAP), an indicator of pulmonary hypertension.	Same	Same
Age of Intended Patient (Years)	40+	Adult (age 22+)	Adult (age 22+)
Machine-Learning based Model	Locked	Same	Same
Input	12-lead ECG tracing, patient age, patient sex	Same	Same
Output	Detection of signs associated with elevated mPAP is provided as “Elevated PH Risk Detected”, “Elevated PH Risk Not Detected”, or “Unclassifiable”.	PH report indicating the likelihood of elevated mPAP	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.	Tablet display (LCD), Mobile App, and Web App.	Same as subject device
Hardware	Tempus ECG-PH is a software-only device. It analyzes ECGs from compatible 12-Lead diagnostic ECG machines with 500Hz digital output.	Seven-Channel Lead Set, PPG Sensor, Capture Device (Tablet).	Same as subject device
Software	Proprietary algorithm and software	Same	Same

Predetermined Change Control Plan (PCCP)

A Predetermined Change Control Plan (PCCP) has been established for the Tempus ECG-PH 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-PH 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 manufacturers.

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.