March 28, 2026

Anumana, Inc.
Taylor Gold West
Director, Regulatory Affairs
One Main Street, Suite 400
East Arcade, 4th Floor
Cambridge, Massachusetts 02142

Re: K252360
Trade/Device Name: ECG-AI Pulmonary Hypertension 12-Lead algorithm
Regulation Number: 21 CFR 870.2380
Regulation Name: Cardiovascular machine learning-based notification software
Regulatory Class: Class II
Product Code: SAT
Dated: July 29, 2025
Received: July 29, 2025

Dear Taylor Gold West:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252360

Device Name
ECG-AI Pulmonary Hypertension 12-Lead algorithm

Indications for Use *(Describe)*
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. ECG-AI PH 12-Lead algorithm is not intended to be a stand-alone diagnostic device for pulmonary hypertension or replace current clinical practice guidelines.

A positive result may suggest the need for further clinical evaluation. Additionally, if the patient is at high risk for pulmonary hypertension, a negative result should not rule out additional clinical evaluation.

ECG-AI PH 12-Lead algorithm should be applied jointly with clinician judgment.

ECG-AI PH 12-Lead algorithm should not be used on ECGs from adults with an implanted pacemaker or 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.

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K252360
510(k) Summary
ECG-AI Pulmonary Hypertension 12-Lead Algorithm

Applicant Name:
Anumana, Inc.
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Cambridge, MA 02142

Primary Contact:
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Date Summary Prepared: March 27, 2026
Proprietary Name of Device: ECG-AI Pulmonary Hypertension 12-Lead algorithm
Common or Usual Name: ECG-AI analysis tool
Classification Panel: Cardiology
Regulation Number: 21 CFR § 870.2380
Regulation Name: Cardiovascular machine-learning notification software
Regulation Class: Class II
Product Code: SAT

Predicate Device(s):
Device Name: ECG-AI Low Ejection Fraction 12-Lead algorithm
Manufacturer: Anumana, Inc.
Application Number: K250652

Device Description

ECG-AI PH 12-Lead algorithm interprets 12-lead ECG voltage time series data using an artificial intelligence-based algorithm. The device analyzes 10 seconds or longer duration of a single 12-lead ECG acquisition, and within seconds detects the presence of pulmonary hypertension in the intended patient population.

ECG-AI PH 12-Lead algorithm is integrated into existing clinical workflows to support overall assessment and to enable physicians to determine whether further workup or referral to a PH specialist is clinically indicated. ECG-AI PH 12-Lead algorithm is intended to be used by clinicians across clinical care settings.

The software module can be integrated into a client application to be accessed by clinicians and results viewed through an Electronic Medical Record (EMR) system or an ECG Management System (EMS)

accessed via a PC, mobile device, or another medical device. In each case, the physician imports 12-lead ECG data in a digital format. The tool analyzes the 10 seconds or longer duration of voltage data collected during a standard 12-lead ECG and outputs a binary result of the likelihood of pulmonary hypertension as an API result.

ECG-AI PH 12-Lead algorithm is not intended to diagnose PH, or to replace current clinical practice guidelines.

ECG-AI Pulmonary Hypertension 12-Lead algorithm is not intended for assessing disease progression or monitoring response to therapy. The ECG-AI Pulmonary Hypertension 12-Lead algorithm is not intended for repeated testing in a short time interval, serial use during the same hospitalization or for serial monitoring.

Indications for Use

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. ECG-AI PH 12-Lead algorithm is not intended to be a stand-alone diagnostic device for pulmonary hypertension or replace current clinical practice guidelines.

A positive result may suggest the need for further clinical evaluation. Additionally, if the patient is at high risk for pulmonary hypertension, a negative result should not rule out additional clinical evaluation.

ECG-AI PH 12-Lead algorithm should be applied jointly with clinician judgment.

ECG-AI PH 12-Lead algorithm should not be used on ECGs from adults with an implanted pacemaker or on ECGs with a paced rhythm.

Technological Characteristics

ECG-AI PH 12-Lead algorithm is provided as a software module packaged in a Docker container to facilitate installation. Technical installation details including access to docker hub, docker hub path, software upgrades, and associated access rights can be found in the Installation Manual ECG-AI Pulmonary Hypertension 12-Lead algorithm. ECG-AI PH 12-Lead algorithm does not provide a graphical user interface (GUI) of its own. It is integrated with other medical systems such as Electronic Medical Record (EMR) systems or ECG Management Systems (EMS). The third-party integrating software will furnish a 12-lead ECG digital waveform as input to ECG-AI PH 12-Lead algorithm and record the output from the device for display or for printing in an offline report.

ECG-AI Pulmonary Hypertension 12-Lead algorithm is solely intended to analyze resting 12-lead ECGs acquired by compatible ECG device models. Automated quality checks are included to ensure that the signal is acquired with appropriate characteristics (e.g., filter, resolution, duration, etc.) from compatible devices, and do not contain excessive noise/artifacts.

ECG-AI Pulmonary Hypertension 12-Lead algorithm is not intended to process other ECGs, such as 6L or 2L ECGs, synthesized 12-lead ECG, data from continuous ECG monitoring, Holter monitoring, telemetry data, data from an ambulatory patient, or ECGs captured when patient is not in resting position.

Predetermined Change Control Plan
This device has been cleared by the U.S. Food and Drug Administration (FDA) with a Predetermined Change Control Plan (PCCP). As part of this authorization, the device software may be updated periodically to enhance performance, including for higher sensitivity and/or specificity.

This modification, related to device performance improvement, will be validated through a multi-center retrospective clinical study that uses a combination of new and existing data. This approach involves supplementing the validation dataset with at least 10% new data for each iteration to ensure it remains current and representative. To be implemented, a modified version must demonstrate improved performance by meeting pre-specified acceptance criteria.

Users will be informed of each applicable update through revised labeling, release notes, or other appropriate communication channels. It is important to review updated instructions and performance summaries accompanying each software version to ensure continued proper use of the device.

Summary of Non-Clinical Performance Data

The performance characteristics for the ECG-AI PH 12-Lead Algorithm have been evaluated with the following non-clinical testing: software verification and validation (per IEC 62304), cybersecurity, labeling verification and validation, and human factors.

Summary of Clinical Performance Data

The performance characteristics for the ECG-AI PH 12-Lead Algorithm have been clinically validated for detection of pulmonary hypertension in adult patients presenting with dyspnea, with PPV and NPV greater than the study's predetermined acceptance criteria, and clinically useful sensitivity and specificity.

Table 1: Performance Characteristics

Performance Characteristic	Value
Sensitivity	73.0%
Specificity	74.4%
Positive Predictive Value (Validation Study)	28.7%
Negative Predictive Value (Validation Study)	95.1%
Positive Predictive Value (Estimated Prevalence of US adults with dyspnea: 4.36%)	11.5%
Negative Predictive Value (Estimated Prevalence of US adults with dyspnea: 4.36%)	98.4%

Algorithm Training

For the development and testing of the algorithm, data were obtained retrospectively from adult patients. Eligible patients were adults who had undergone RHC or had an echocardiogram with results available in digitized form and voltage–time data from at least one standard 10-s, 12-lead ECG. Patients with PH were defined as those with mean pulmonary arterial pressure (mPAP) >20 mmHg at rest if the patient had a right heart catheterization (RHC) performed, or if a patient could not be classified as PH positive or PH negative by RHC, a high probability of PH by echocardiogram, defined as tricuspid regurgitation velocity (TRV) >3.4 m/s at baseline. Control patients were defined as those with mPAP ≤20 mmHg on all available RHCs, or if no RHC was performed, TRV ≤2.8 m/s on all available echocardiograms.

A total of 282,927 adult patients (PH patients n=46,157; control patients n=236,770) with paired ECGs were retrospectively identified from Mayo Clinic. Among these patients, 259,227 had an ECG within 30 days before or after the date of PH diagnosis, or an ECG on or before last screening (for control patients), and were included in the diagnostic dataset. The diagnostic dataset included 39,823 PH patients (17,688 patients with dyspnea code) and 219,404 control patients (40,251 with dyspnea code). This dataset was sub-divided into the train (n=18,987 PH patients; n=105,260 controls), tune (n=4,661 PH; n=26,146 controls) and test (n=16,175 PH; n=87,998 controls) sets. The ECG-AI PH 12-Lead algorithm was trained on ECGs from the Mayo Clinic database taken +/-1 month of PH diagnosis (diagnostic dataset). Within the diagnostic test set, a total of 23,310 patients (n=7,155 PH patients, n=16,155 control patients) had a dyspnea ICD code recorded on or prior to an ECG and the diagnostic RHC or echocardiogram, and were used to test performance within the intended use population. Performance analyses were also conducted in subgroups of age, sex, and race.

Summary of Clinical Validation

Study Design

The performance profile of the Anumana ECG-AI PH 12-Lead algorithm was validated in a retrospective study of 21,066 patient records across 5 health systems across the United States. The objective of the study was to establish the diagnostic performance of the device for the purpose of detecting the presence of a pulmonary hypertension in a clinically and demographically diverse population. The inclusion criteria for a subject was: age ≥ 18 with at least one dyspnea ICD code, at least one of either a right heart catheterization (RHC) with mean pulmonary arterial pressure (mPAP) measured or an echocardiogram (echo) with tricuspid regurgitation velocity (TRV) measured any time on or after a dyspnea ICD code; and the availability of at least one digital 12-lead ECG taken on or after a dyspnea ICD code and prior to or up to 30 days following an RHC or echo. The primary analysis was conducted using RHC and echo criteria to define cases and controls.

Summary of Study Results

The 5 sites contributed to the final pool of 21,066 patient records. The study sample was representative of the US population and was 70.4% White, 16.6% Black/African American, 0.4% American Indian or Alaska Native, 2.1% Asian, 0.3% Native Hawaiian or Pacific Islander, 0.1% Multiracial, and 10.0% Other or Unknown, with 5.6% Hispanic or Latino. The sample consisted of 50.1% male and 49.9% female participants. 19.6% of participants were under age 50, 17.4% were 50-59, 26.8% were 60-69, and 36.2% were over 70.

Within this enriched study sample, a total of 10,036 PH Positive cases were identified from 21,066 records. The Anumana ECG-AI PH 12-Lead device achieved a sensitivity of 73.0% (95% CI of 72.1% to 73.9%), and a specificity of 74.4% (95% CI of 73.5% to 75.2%).

The PPV and NPV were analyzed using an adjusted prevalence of 4.36% based on a data set comprised of 183,348 unique adult patients who presented with an ICD code for dyspnea (ICD9: 786.0, 786.05; ICD10: R06.00, R06.01, R06.02, R06.09) and had received a standard 12-lead ECG. This dataset is from the Mayo Clinic, which includes tertiary specialty centers as well as community care facilities and is intended to represent an estimate of prevalence of PH in a generalized dyspnea adult population in a broad real-world setting. This resulted in a PPV of 11.5% (95% CI of 11.2% to 11.8%) and NPV of 98.4% (95% CI of 98.3% to 98.4%). Performance is shown in Table 1.

Subgroup analyses results provided in **Table 2: Subgroup Analyses.**

Subgroup Analyses

Subgroup assessments of diagnostic performance were conducted to evaluate the device across varying clinical and demographic populations. Table 2 presents the sensitivity and specificity of the ECG-AI PH 12-Lead algorithm across key patient subgroups. Note: Additional performance evaluations across specific clinical sites, ECG manufacturers and device models, patient comorbidities, and underlying ECG rhythms were conducted and maintained comparable safety profiles. Full details are available in the Clinical Study Report.

Table 2: Subgroup Analyses

Subgroup	Sensitivity (95% CI) *(n/N)*	Specificity (95% CI) *(n/N)*
Overall Performance	73.0% (72.1%, 73.9%) *(7,328/10,036)*	74.4% (73.5%, 75.2%) *(8,202/11,030)*
PH Screen Type		
Echo	80.8% (79.0%, 82.5%) *(1,629/2,017)*	75.8% (74.9%, 76.7%) *(6,922/9,128)*
Right Heart Catheterization (RHC)	71.1% (70.1%, 72.1%) *(5,699/8,019)*	67.3% (65.1%, 69.4%) *(1,280/1,902)*
Biological Sex		
Female	68.9% (67.5%, 70.2%) *(3,226/4,685)*	78.2% (77.1%, 79.3%) *(4,550/5,818)*
Male	76.7% (75.5%, 77.8%) *(4,102/5,351)*	70.1% (68.8%, 71.3%) *(3,652/5,212)*
Age at Encounter		
< 50 Years	77.5% (75.5%, 79.4%) *(1,409/1,819)*	79.4% (77.7%, 81.0%) *(1,835/2,312)*
50 – 59 Years	72.7% (70.6%, 74.8%) *(1,300/1,787)*	76.4% (74.4%, 78.3%) *(1,437/1,882)*
60 – 69 Years	69.9% (68.1%, 71.5%) *(1,958/2,803)*	74.6% (73.0%, 76.2%) *(2,117/2,838)*
70+ Years	73.4% (71.9%, 74.8%) *(2,661/3,627)*	70.4% (68.9%, 71.8%) *(2,813/3,998)*
Race		
American Indian/Alaska Native	80.9% (66.7%, 90.9%) *(38/47)*	77.1% (59.9%, 89.6%) *(27/35)*
Asian	76.6% (69.5%, 82.8%) *(128/167)*	75.9% (70.4%, 80.9%) *(208/274)*
Black	80.4% (78.6%, 82.1%) *(1,585/1,971)*	71.6% (69.2%, 73.8%) *(1,098/1,534)*
Multiracial	54.5% (23.4%, 83.3%) *(6/11)*	78.9% (54.4%, 93.9%) *(15/19)*
Native Hawaiian or Other Pacific Islander	80.6% (64.0%, 91.8%) *(29/36)*	66.7% (43.0%, 85.4%) *(14/21)*
White	69.8% (68.7%, 70.9%) *(4,725/6,769)*	74.7% (73.7%, 75.6%) *(6,027/8,068)*
Other or Unknown	78.9% (76.3%, 81.4%) *(817/1,035)*	75.3% (72.7%, 77.9%) *(813/1,079)*
Ethnicity		
Hispanic or Latino	76.9% (73.1%, 80.5%) *(407/529)*	76.6% (73.2%, 79.8%) *(498/650)*
Not Hispanic or Latino	72.8% (71.9%, 73.7%) *(6,844/9,400)*	74.1% (73.2%, 74.9%) *(7,501/10,124)*
Unknown	72.0% (62.5%, 80.2%) *(77/107)*	79.3% (73.8%, 84.1%) *(203/256)*

Body Mass Index (BMI)		
< 30 kg/m²	76.7% (75.5%, 77.9%) *(3,624/4,725)*	74.5% (73.3%, 75.6%) *(4,135/5,552)*
30 – 34 kg/m²	70.3% (68.2%, 72.3%) *(1,372/1,953)*	76.5% (74.6%, 78.4%) *(1,459/1,906)*
35+ kg/m²	64.2% (62.3%, 66.2%) *(1,526/2,376)*	76.6% (74.5%, 78.6%) *(1,298/1,695)*
Unknown	82.1% (79.5%, 84.4%) *(806/982)*	69.8% (67.7%, 71.9%) *(1,310/1,877)*

Substantial Equivalence

The subject device, Anumana ECG-AI PH 12-Lead algorithm, is substantially equivalent to the predicate, ECG-AI LEF 12-Lead algorithm (K250652). The devices have equivalent intended uses, principles of operation, and technical characteristics. Where differences occur between the subject device and the predicates, results of clinical performance and results of non-clinical verification and validation demonstrate that the subject device does not raise new questions of safety and effectiveness.

Table 3: Substantial Equivalence Comparison of Subject Device to the Predicate

	Subject Device	Predicate	Discussion
Manufacturer	Anumana Inc.	Anumana Inc.	
Product Name	ECG-AI PH 12-Lead algorithm (v3.1.0)	ECG-AI LEF 12-Lead algorithm (v2.5.0)	
Application No.	K252360	K250652	
Product Code	SAT	QYE	Equivalent. The SAT product code is for Pulmonary Hypertension, specifically. QYE is for low ejection fraction. Both Product Codes are assigned to the Regulation number 21 CFR 870.2380.
Regulation No.	21 CFR 870.2380	21 CFR 870.2380	Identical.
Regulation Name	Cardiovascular machine learning-based notification software	Cardiovascular machine learning-based notification software	Identical.
Intended Use/ Indications for Use	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. ECG-AI PH 12-Lead algorithm is not intended to be a stand-alone	The ECG-AI LEF 12-Lead algorithm is software intended to aid in earlier detection of Left Ventricular Ejection Fraction (LVEF) less than or equal to 40% in adults (aged 18 and above) at risk for heart failure. This population includes, but is not limited to: • patients with cardiomyopathies • patients who are post-myocardial infarction • patients with aortic stenosis	Equivalent. The subject device intended use is equivalent to the predicate in that both are intended to aid in earlier detection of a cardiovascular disease or condition. The subject device and predicate have equivalent language to address the need for further clinical evaluation to establish diagnosis since neither device is intended for standalone use.

	Subject Device	Predicate	Discussion
Manufacturer	Anumana Inc.	Anumana Inc.	
Product Name	ECG-AI PH 12-Lead algorithm (v3.1.0)	ECG-AI LEF 12-Lead algorithm (v2.5.0)	
	diagnostic device for pulmonary hypertension or replace current clinical practice guidelines. A positive result may suggest the need for further clinical evaluation. Additionally, if the patient is at high risk for pulmonary hypertension, a negative result should not rule out additional clinical evaluation. ECG-AI PH 12-Lead algorithm should be applied jointly with clinician judgment. The ECG-AI PH 12-Lead algorithm should not be used on ECGs from adults with an implanted pacemaker or on ECGs with a paced rhythm.	• patients with chronic atrial fibrillation • patients receiving pharmaceutical therapies that are cardiotoxic, and • postpartum women. The ECG-AI LEF 12-Lead algorithm is not intended to be a stand-alone diagnostic device for cardiac conditions, should not be used for monitoring of patients, and should not be used on ECGs with a paced rhythm. A positive result may suggest the need for further clinical evaluation in order to establish a diagnosis of Left Ventricular Ejection Fraction (LVEF) less than or equal to 40%. Additionally, if the patient is at high risk for the cardiac condition, a negative result should not rule out further non-invasive evaluation. The ECG-AI LEF 12-Lead algorithm should be applied jointly with clinical judgement.	
Diagnostic Application	Pulmonary Hypertension	Left Ventricular Ejection Fraction (LVEF) less than or equal to 40%	Equivalent. The predicate device is designed for a different disease population but the subject device similarly helps to detect Pulmonary Hypertension. Additional clinical validation was conducted to support equivalence.

	Subject Device	Predicate	Discussion
Manufacturer	Anumana Inc.	Anumana Inc.	
Product Name	ECG-AI PH 12-Lead algorithm (v3.1.0)	ECG-AI LEF 12-Lead algorithm (v2.5.0)	
Target Population	Adults presenting with dyspnea	Adults at risk for heart failure	Equivalent. Both devices are intended to target adults with cardiovascular symptoms and/or risk factors.
Intended User	Clinicians	Clinicians	Identical.
Principal of Operation	Machine learning-based algorithm	Machine learning-based algorithm	Identical.
Data Acquisition	Acquires data from 12-L ECGs	Acquires data from 12-L ECGs	Identical. Subject device and predicate both use 12-L ECGs for data acquisition.
Device Output Format	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".	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".	Identical. Subject and predicate devices provide binary output based on calculations from data for a given disease state to indicate likelihood of disease.
Cybersecurity	Compliant with FDA Guidance on Cybersecurity	Compliant with FDA Guidance on Cybersecurity	Identical. Subject and predicate device algorithms are compliant with FDA Guidance and Standards for Cybersecurity.

Benefit-Risk Determination

The probable benefits of the ECG-AI PH outweigh the probable risks when used as an aid in the early detection of elevated mean pulmonary arterial pressure (mPAP), an indicator of pulmonary hypertension (PH), in adult patients with dyspnea.

Probable Benefits: The primary benefit of the device is the ability to provide an immediate, non-invasive, and accessible result for PH detection using a standard 12-lead ECG, as PH is frequently underdiagnosed or diagnosed late in the disease course. In the clinical validation study, the device demonstrated Sensitivity (73.0%) and Specificity (74.4%), as well as a Positive (11.5%) and Negative Predictive Value (98.4%) at the projected intended use prevalence (4.36%).

Probable Risks and Mitigation: The primary risks associated with the device are False Negative and False Positive results.

- **False Negatives:** A false negative may result in a delayed diagnosis of PH. The device is indicated as an adjunct to clinical judgment; a negative result does not preclude further workup if clinical suspicion remains high.
- **False Positives:** A false positive result may lead to unnecessary follow-up testing or referral to a specialist. The device is intended to be used as an adjunct and should be used in context of the clinician's clinical suspicion for PH.
- **Signal Quality:** The device incorporates a robust quality assessment module that prevents analysis of poor-quality signals, outputting an "ERROR" rather than an unreliable prediction, further mitigating the risk of incorrect outputs due to noise or artifacts.

Overall Conclusion: The clinical and non-clinical data demonstrate that the ECG-AI PH is substantially equivalent to the predicate device for its intended use. The performance profile supports its use as a detection aid to prioritize patients for downstream diagnostic evaluation.