February 13, 2026

Measure Labs, Inc. (DBA PreemptiveAI, Inc.)
Matt Whitehill
Chief Technology Officer
2790 Mosside Blvd.
Monroeville, Pennsylvania 15146

Re: K250233
Trade/Device Name: PreemptiveAI Clinical SDK
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter And Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: February 10, 2026
Received: February 11, 2026

Dear Matt Whitehill:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

Your device is also subject to, among other requirements, the Quality 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,

JENNIFER W. SHIH -S

Jennifer Kozen
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.*

Submission Number *(if known)*

K250233

Device Name

PreemptiveAI Clinical SDK

Indications for Use *(Describe)*

The PreemptiveAI Clinical SDK is intended for noninvasive spot measurement of pulse rate. The measurement is based on video recording of the subject's fingertip using a smartphone camera. It is designed for use when the subject is still. It is indicated for individuals 18 years of age or older not requiring critical care or continuous vital signs monitoring. It is not intended for use in patients with known or suspected heart arrhythmias.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

| | |
|---|---|
| **Company Address:** | Measure Labs, Inc. (DBA PreemptiveAI, Inc.)<br>2801 Alaskan Way, Suite 302, Seattle, WA 98121-1134 |
| **Primary Contact Person:** | Matt Whitehill<br>Chief Technology Officer |
| **Date Prepared:** | February 10, 2026 |
| **Device Name:** | PreemptiveAI Clinical SDK |
| **Classification:** | 21 CFR 870.2920 Telephone electrocardiograph transmitter and receiver<br><br>Product Code: DXH<br><br>Regulatory Class: II |
| **Predicate Device:** | Fibricheck (K232804) |
| **Indications for Use:** | The PreemptiveAI Clinical SDK is intended for noninvasive spot measurement of pulse rate. The measurement is based on video recording of the subject's fingertip using a smartphone camera. It is designed for use when the subject is still. It is indicated for individuals 18 years of age or older not requiring critical care or continuous vital signs monitoring. It is not intended for use in patients with known or suspected heart arrhythmias. |
| **Device Description:** | The PreemptiveAI Clinical SDK is a Software as a Medical Device (SaMD) that utilizes a smartphone to noninvasively measure pulse rate (PR). Designed for integration into third-party mobile applications, the SDK operates on Android and iOS devices, enabling spot-check pulse rate measurements.<br><br>The PreemptiveAI Clinical SDK captures a 30-second fingertip video with the smartphone's back camera. The software extracts a photoplethysmography (PPG) waveform, partitions that 30-second |

signal into overlapping 10-second windows, and applies an autocorrelation-based signal quality check. A proprietary deep learning algorithm then calculates pulse rate for every window that passes the quality screen. The value shown to the user is the average of all passing windows, and if every window fails the screen, no rate is reported and a “Low Signal Quality” prompt is displayed.

The SDK outputs a single pulse-rate value; it is not intended for automated analysis or arrhythmia detection. The PreemptiveAI Clinical SDK is not intended for use with alarm systems.

**Technological Characteristics**

The PreemptiveAI Clinical SDK uses photoplethysmography (PPG) technology to capture and analyze blood flow signals. The SDK comprises a mobile SDK for integration into a 3rd-party app, backend server, and locked deep learning model for pulse rate prediction.

**Substantial Equivalence Comparison Summary:**

| | **Subject Device (K250233)** | **Predicate Device (K232804)** |
|---|---|---|
| **Manufacturer** | PreemptiveAI | Fibricheck |
| **Device Name** | PreemptiveAI Clinical SDK | Fibricheck |
| **Indications for Use** | The PreemptiveAI Clinical SDK is intended for noninvasive spot measurement of pulse rate. The measurement is based on video recording of the subject’s fingertip using a smartphone camera. It is designed for use when the subject is still. It is indicated for individuals 18 years of age or older not requiring critical care or continuous vital signs monitoring. It is not intended for use in patients with known or suspected heart arrhythmias. | Fibricheck is indicated for self-testing by patients who have been diagnosed with, or are susceptible to developing, atrial fibrillation and who would like to monitor and record their heart rhythms on an intermittent basis. |
| **Regulation names and numbers** | 21 CFR 870.2920 Telephone electrocardiograph transmitter and receiver. | 21 CFR 870.2920 Telephone electrocardiograph transmitter and receiver. |
| **Product codes and classifications** | Code: DXH<br>Class: II | Code: DXH<br>Class: II |

| | | |
|---|---|---|
| **User Population** | Adults 18 years or older not requiring critical care or continuous vital signs monitoring. | Adults. Patients, who have been diagnosed with, or are susceptible to developing, atrial fibrillation. |
| **Rx / OTC** | Rx | Rx |
| **Component** | Software Only | Software Only |
| **Measurement Type** | Spot Check | Spot Check |
| **Measurement Site** | Fingertip | Fingertip |
| **Single Patient Use** | Yes | Yes |
| **Outputs** | Pulse Rate | Pulse Rate<br>Irregular Heart Rhythm Notification |
| **Device Description** | PreemptiveAI Clinical SDK uses reflectance photoplethysmography (PPG) to estimate a user's pulse rate through the existing camera hardware on a smartphone. Specifically, the SDK analyzes optical signals captured from the fingertip, leveraging the phone's camera and flash to detect changes in blood volume associated with each cardiac cycle. The measured pulse rate is displayed as a periodic spot check, enabling users to track their pulse rate in non-critical care environments. | FibriCheck is medical device software that determines heart rhythm conditions, with a primary focus on the detection of Atrial Fibrillation. It makes use of optical sensing from a mobile device to collect photoplethysmogram data (PPG data). The recordings can be shared optionally with a physician or monitoring service. |
| **Technology Characteristics** | The PreemptiveAI Clinical SDK measures pulse rate through an optical camera-based mechanism. It is intended to run on Android and iOS mobile devices, capturing video of the fingertip to compute the blood volume signal, then utilizing a locked deep learning ML model to calculate pulse rate from this signal. | FibriCheck obtains waveform via Mobile Platform camera and displays signal in real time on the Mobile Platform device with an arrhythmia index. Text display (green, amber, or blue) indicates heart regularity or irregularity. All tests are stored. |
| **Measurement Window** | 30 seconds | 1 minute |
| **Pulse Rate Range** | 50-125 bpm | Unknown |

| | | |
|---|---|---|
| **Pulse Rate Performance (Error Level)** | +/- 3 bpm | Unknown |

**Non-Clinical Software testing:**

- **Verification and Validation** - Verification and validation testing of the PreemptiveAI Clinical SDK was conducted to ensure the software meets the design requirements and intended use. This testing included a full characterization of software technical parameters and algorithms.
- **Hardware Compatibility** - Testing was performed on 4 different smartphone models during Clinical Testing, confirming the SDK functions appropriately across a range of devices.
- **Human Factors** - A human factors study was conducted to evaluate potential risks associated with usability. The testing included evaluation of the device's response to user errors and the user's reaction to controls and mitigations.
- **Bench Testing** - Bench testing confirmed the device is accurate across its claimed 50–125 bpm operational range and behaves in a predictable, fail-safe manner by suppressing readings outside these boundaries. Further bench testing also demonstrated appropriate algorithm behavior in the presence of heart arrhythmias.
- **Cybersecurity Testing** - Cybersecurity testing was conducted including vulnerability analysis. Documentation was provided to show adequate cybersecurity measures have been taken and will be monitored and updated throughout the device life cycle.

**Summary of Clinical Testing:**

A clinical study was conducted to evaluate the performance of the PreemptiveAI Clinical SDK for noninvasive pulse rate measurement and to demonstrate its substantial equivalence to the predicate device. The study enrolled 111 participants, aged 18 years and older, representing a diverse demographic distribution across sex, age, race, and skin tone. Participants were recruited from a general population, ensuring applicability to a broad user base.

The pulse rate obtained by the PreemptiveAI Clinical SDK was compared to the heart rate obtained by the reference device. The Average Root Mean Square (ARMS) and its 95% confidence interval were calculated. The hypothesis that the PreemptiveAI Clinical SDK can measure pulse rate within ± 3 BPM ARMS is accepted. Sub-group accuracy was calculated to ensure adequate performance. Based on the results of the study, the PreemptiveAI Clinical SDK is effective at determining pulse rate in the intended use population.

## Demographic characteristics of the clinical testing dataset

| **Description** | | **Number** |
|---|---|---|
| **Subjects** | **Total** | 111 |
| Age | 18-29 | 21 |
| | 30-39 | 29 |
| | 40-49 | 17 |

| | | |
|---|---|---|
| | 50-59 | 16 |
| | 60-69 | 11 |
| | 70+ | 17 |
| Sex | Male | 78 |
| | Female | 33 |
| Race / Ethnicity (participants could select more than 1 option) | American Indian / Alaskan Native | 4 |
| | Hispanic / Latino | 7 |
| | South Asian | 10 |
| | East Asian | 13 |
| | Black African/American | 20 |
| | White | 58 |
| | Other | 4 |
| | Prefer not to answer | 3 |
| Skin Tone (Fitzpatrick scale) | Type I and II | 64 |
| | Type III and IV | 28 |
| | Type V and VI | 19 |
| Arrhythmia | No Arrhythmia | 77 |
| | Arrhythmia | 34 |
| Atrial Fibrillation | No Atrial Fibrillation | 100 |
| | Atrial Fibrillation | 11 |

**Conclusion:**

The PreemptiveAI Clinical SDK has been found to be substantially equivalent to the predicate device with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device.