April 4, 2025

Whoop, Inc.
Shweta Parwe
Quality Systems and Regulatory Affairs Manager
One Kenmore Sq
Boston, Massachusetts 02215

Re: K243236
Trade/Device Name: WHOOP ECG (electrocardiogram) Feature (1.0)
Regulation Number: 21 CFR 870.2345
Regulation Name: Electrocardiograph Software For Over-The-Counter Use
Regulatory Class: Class II
Product Code: QDA
Dated: March 3, 2025
Received: March 5, 2025

Dear Shweta Parwe:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Kimberly N. Crowley -S

Digitally signed by Kimberly N. Crowley -S

For: 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.

510(k) Number *(if known)*
K243236

Device Name
WHOOP ECG (electrocardiogram) Feature

Indications for Use *(Describe)*
The WHOOP ECG Feature is a software-only mobile medical application intended for use with the WHOOP Strap to create, record, store, transfer, and display a single-channel electrocardiogram (ECG) qualitatively similar to a Lead I ECG. The WHOOP ECG Feature determines the presence of atrial fibrillation (AFib), normal sinus rhythm, low heart rate (≤ 50 beats per minute [bpm]), and high heart rate (≥ 100 bpm) on a classifiable waveform. The WHOOP ECG Feature is not recommended for users with other known arrhythmias.

The WHOOP ECG Feature is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG Feature are intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without the consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and is not intended to replace traditional methods of diagnosis or treatment.

The WHOOP ECG Feature is intended for use by adults 22 years of age and older.

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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WHOOP®

510(k) Summary – K243236

Contact Details

Applicant Name	WHOOP, Inc.
Applicant Address	One Kenmore Sq, Boston, MA 02215 1-857-284-1532
Primary Correspondent	Shweta Parwe Quality Systems and Regulatory Affairs Manager whoop-med-device@whoop.com
Secondary Correspondent	Niharika Trivedi Regulatory Affairs Specialist II niharika.trivedi@whoop.com
Date Prepared	March 3, 2025

Device Name

Device Trade Name	WHOOP ECG (electrocardiogram) Feature
Classification Name	Electrocardiograph software for over-the-counter use
Regulatory Class	Class II
Regulation Number	21 CFR 870.2345
Product Code(s)	QDA
Review Panel	Cardiovascular

Legally Marketed Predicate Device

Predicate #	Predicate Manufacturer	Predicate Trade Name	Product Code
K201525	Apple Inc.	ECG App (2.0)	QDA

Device Description Summary

The WHOOP ECG Feature is a software-only medical mobile application integrated into the consumer (non-device) WHOOP System. It consists of three medical device modules: ECG Strap Module, ECG Phone Module, and ECG Cloud Module.

The feature is designed to create, record, store, transfer, and display a single-channel electrocardiogram (ECG), qualitatively similar to a Lead I ECG. It analyzes ECG recordings collected via the ECG electrodes on the WHOOP Strap.

The ECG Strap Module firmware is integrated within the WHOOP Strap's firmware. The ECG Strap Module firmware contains the FDA-cleared B-Secur HeartKey Software Library (K200884) which is used to provide classification for a 30-second ECG spot check recording into corresponding WHOOP ECG Feature outputs: Normal Sinus Rhythm; AFib; Low Heart Rate; High Heart Rate; Inconclusive; and Unsuccessful Reading. Users must opt in and complete onboarding through the ECG Phone Module within the WHOOP Mobile Application before accessing the ECG Feature.

The ECG Cloud Module processes requests for ECG report generation. Users can download ECG reports in PDF format to their mobile device or share them via applications such as email or messaging.

The WHOOP ECG Feature is not intended to replace traditional diagnostic or treatment methods.

Intended Use/Indications for Use

The WHOOP ECG Feature is a software-only mobile medical application intended for use with the WHOOP Strap to create, record, store, transfer, and display a single-channel electrocardiogram (ECG)

qualitatively similar to a Lead I ECG. The WHOOP ECG Feature determines the presence of atrial fibrillation (AFib), normal sinus rhythm, low heart rate (≤ 50 beats per minute [bpm]), and high heart rate (≥ 100 bpm) on a classifiable waveform. The WHOOP ECG Feature is not recommended for users with other known arrhythmias.

The WHOOP ECG Feature is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG Feature are intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without the consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and is not intended to replace traditional methods of diagnosis or treatment.

The WHOOP ECG Feature is intended for use by adults 22 years of age and older.

Table 1: Technological Comparison

	Subject Device WHOOP ECG (electrocardiogram) Feature (Subject Device K243236)	**Predicate Device Apple Inc. ECG App (2.0) (Predicate Device K201525)**	**Discussion**
Product Code	QDA	QDA	Identical to the predicate
Regulation	21 CFR 870.2345	21 CFR 870.2345	Identical to the predicate
Device Class	Class II	Class II	Identical to the predicate
Indications for Use	The WHOOP ECG Feature is a software-only mobile medical application intended for use with the WHOOP Strap to create, record, store, transfer, and display a single-channel electrocardiogram (ECG) qualitatively similar to a Lead I ECG. The WHOOP ECG Feature determines the presence of atrial fibrillation (AFib), normal sinus rhythm, low heart rate (≤ 50 beats per minute [bpm]), and high heart rate (≥ 100 bpm) on a classifiable waveform. The WHOOP ECG Feature is not recommended for users with other known arrhythmias. The WHOOP ECG Feature is intended for over-the-counter (OTC) use. The ECG data	The ECG app is a software-only mobile medical application intended for use with the Apple Watch to create, record, store, transfer, and display a single-channel electrocardiogram (ECG) similar to a Lead I ECG. The ECG app determines the presence of atrial fibrillation (AFib), sinus rhythm, and high heart rate (no detected AF with heart rate 100-150 bpm) on a classifiable waveform. The ECG app is not recommended for users with other known arrhythmias. The ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the ECG app is intended for informational use only. The user is not intended to interpret or take clinical action	Indications for use between the WHOOP ECG Feature and the Apple ECG App 2.0 (K201525) are substantially equivalent.

	displayed by the ECG Feature are intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without the consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from normal sinus rhythm and is not intended to replace traditional methods of diagnosis or treatment. The WHOOP ECG Feature is intended for use by adults 22 years of age and older.	based on the device output without the consultation of a qualified healthcare professional. The ECG waveform is meant to supplement rhythm classification for the purposes of discriminating AFib from sinus rhythm and is not intended to replace traditional methods of diagnosis or treatment. The ECG app is not intended for use by people under 22 years old.	
Mechanism of Use	Users input from consumer wrist-worn devices to detect the electrical potential differences between the electrodes, generate an ECG waveform and assess ECG for rhythm abnormality.	Users input from consumer wrist-worn devices to detect the electrical potential differences between the electrical sensors, generate an ECG waveform and assess ECG for rhythm abnormality.	Identical to the predicate
Intended Use Environment	Over-the-counter (OTC)	Over-the-counter (OTC)	Identical to the predicate
Intended User Population	Individuals - 22 years and older. It is not recommended for users with arrhythmias other than AFib.	Individuals - 22 years and older. It is not recommended for users with arrhythmias other than AFib.	Identical to the predicate
Anatomical Site	Left-hand fingers to the right wrist or vice versa on a consumer-grade electronic.	Left-hand fingers to the right wrist or vice versa on a consumer-grade electronic.	Identical to the predicate
Data Storage	ECG Data is transmitted and stored on the ECG Cloud Module	ECG Data is transmitted and stored on the ECG Phone App	Identical to the predicate
ECG Channels	Single Channel Lead I	Single Channel Lead I	Identical to the predicate

User Interface	ECG Phone Module (WHOOP Mobile Application)	Device App and Phone App	Identical to the predicate
Use Method	Record a 30-second ECG on the wrist-worn device and receive results determining the presence of Atrial Fibrillation, Low Heart Rate, High Heart Rate, Inconclusive, or Sinus Rhythm	Record a 30-second ECG on the wrist-worn device and receive results determining the presence of Atrial Fibrillation, Low Heart Rate, High Heart Rate, Inconclusive, or Sinus Rhythm	Identical to the predicate
ECG Session Classification Results	- Low Heart Rate (≤ 50 bpm) - Normal Sinus Rhythm (51 - 99 bpm) - High Heart Rate - No Atrial Fibrillation Detected (100-150 bpm) - Atrial Fibrillation (51-99 bpm) - Atrial Fibrillation - High Heart Rate (100-150 bpm) - High Heart Rate (> 150 & <=200 bpm) - Inconclusive -ECG Reading Unsuccessful	- Low Heart Rate (< 50 bpm) - Sinus Rhythm (50-99 bpm) - High Heart Rate (No AFib) (100-150 bpm) - Atrial Fibrillation (50-99 bpm) - Atrial Fibrillation High Heart Rate (100-150 bpm) - Inconclusive - Poor Recording - High Heart Rate (> 150 bpm)	Substantially Equivalent. The WHOOP output category 'Unreadable' is analogous to the predicate's 'Poor Recording,' indicating that there is too much artifact or noise in the waveform to perform arrhythmia classification.
ECG Waveform Display	Qualitatively similar to a Lead I ECG waveform displayed as a pdf on the WHOOP Mobile application.	Similar to a Lead I ECG displayed as a pdf on the Mobile app	Clinical validation of the WHOOP ECG Feature demonstrated acceptable signal quality and reliability in capturing and displaying ECG waveforms. WHOOP also conducted a quantitative assessment to evaluate the similarity between ECG waveforms generated by the WHOOP device and those from a 12-lead reference system. These results support that the differences in technological characteristics do not raise new questions of

			safety or effectiveness.
Compatibility with Intended Platform	WHOOP Strap version - WHOOP MG Apple iPhone with minimum iOS version 18.0 Android Phones compatible with minimum Android version 12.0	iOS version 14.0 WatchOS version 7.0 Apple Watch Series 4, Apple Watch Series 5 iPhone 6s - iPhone 11 models	Substantially equivalent. Similar to the predicate, there is compatibility with iOS phone platforms and specified wearable hardware. Additionally, WHOOP is compatible with the Android operating system. The software verification testing demonstrates these requirements for compatibility are met.

Non-Clinical Testing

Software Verification Testing

Software verification was completed, and documentation was provided as recommended by the *Guidance for Industry and FDA Staff Content of Premarket Submissions for Device Software Functions (issued June 14, 2023)* for a basic level device. Cybersecurity testing, labeling, and a management plan were provided as recommended by the *Guidance for Industry and FDA Staff Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (issued September 27, 2023)*.

Database Testing

In compliance with special controls established under 21 CFR 870.2345(3), database testing using a previously adjudicated dataset was conducted as per ANSI/AAMI EC57:2012(R2020).

Electromagnetic compatibility (EMC), Electrical Safety, and Signal Acquisition Testing

Testing was performed on the commercial WHOOP system, demonstrating it meets all necessary specifications to host the subject SaMD. The testing also supports substantial equivalence for WHOOP system's ability to reliably acquire ECG signals suitable for analysis and display, comprehensive electromagnetic compatibility (EMC), electrical safety, and signal acquisition performance. The following standards were utilized:

- Thermal safety requirements under IEC 62368-1: 2018
- Applicable RF and EMC requirements under EN 301-489-1 v2.2.3:2019, EN 301-489-3 v2.3.2:2023, EN 301-489-17 v3.2.5:2022 and FCC 47 CFR Part 15 Subpart B:2024
- Medical Electrical Equipment - IEC 60601-2-47:2012 (Basic Safety and Essential Performance of Ambulatory ECG Systems)

Human Factors Validation

To address special control (4) under 21 CFR 870.2345, WHOOP conducted a human factors validation study with representative users of AFib and non AFib users in accordance with IEC 62366-1:2015

Medical devices – Part 1: Application of usability engineering to medical devices and the FDA Guidance Document Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff (issued February 3, 2016). The results of this study were positive and demonstrated that the user can correctly use the device by solely reading the device labeling and also correctly interpret the device output and understand when to seek medical care. This testing further supports evidence of substantial equivalence.

Testing was also conducted to evaluate consumers' ability to accurately self-select if the ECG Feature is intended for them. This testing involved 51 participants, comprising both individuals for whom the ECG Feature is intended, as well as non-intended user population. This testing concluded that users can adequately self-select if the device is intended for them.

Clinical Testing

The WHOOP ECG Feature's ability to accurately classify an ECG recording into AFib and sinus rhythm was validated in a clinical trial of approximately 540 subjects - 255 were enrolled in the AFib cohort, 285 were enrolled in the normal sinus rhythm cohort. The mean age of enrolled subjects was 60.4. Rhythm classification of a 12-lead ECG by a cardiologist was compared to the rhythm classification of a simultaneously collected ECG from the WHOOP feature. The ECG feature demonstrated 96.2% sensitivity in classifying AFib (HR 50-150 bpm) and 99.4% specificity in classifying sinus rhythm (HR 50-150 bpm) in classifiable recordings.

During this study, the WHOOP ECG Feature determined 11% of recordings were inconclusive. When including all of these inconclusive recordings, the probability that the WHOOP ECG Feature would return an AFib result for a subject in AFib was 87.47% and 96.59% for a SR result for subjects in sinus rhythm. Real-world performance for inconclusive and poor recording may differ.

Subgroup analysis indicated sensitivity ranged from 95.1% - 100% across all age groups, and specificity ranged from 97.6% - 100%. Specificity and sensitivity estimates for females were 99.3% and 98.9% and 99.6% and 95.4% for males. Specificity and sensitivity estimates for subjects identifying as White were 99.4% and 96.3%, 99.3% and 96.2% for Black or African American, 100% and 71.4% for American Indian or Alaska Native and 100.0% each for subjects identifying as Asian and Other. The low specificity observed in the American Indian or Alaska Native subgroup is likely due to the smaller sample size of this population in the study.

The morphology of the waveform was also tested in this clinical trial by a comprehensive visual assessment of the WHOOP waveforms in comparison to the 12-lead reference. The ECG Feature produced waveforms with acceptable signal quality 99.4% of the time.

WHOOP conducted a quantitative assessment comparing ECG waveforms from the WHOOP device to a 12-lead reference ECG. Similarity was evaluated by comparing key features: PR interval, QRS duration, R-wave amplitude, and RR interval.

Conclusions

The subject device and predicate devices have the same intended use and the same key technological characteristics. The WHOOP ECG Feature was assessed and evaluated through non-clinical and clinical performance testing including the special controls requirements under 21 CFR 870.2345. The testing results demonstrate that the minor differences between the subject and predicate device do not raise new questions of safety and effectiveness and support a substantial equivalence determination. The WHOOP ECG Feature is substantially equivalent to the Apple ECG App 2.0.