June 15, 2025

Withings
Aline Criton
Regulatory Affairs Manager
2 Rue Maurice Hartmann
Issy-Les-Moulineaux, Île-de-France 92130
France

Re: K240795
Trade/Device Name: Withings ECG App
Regulation Number: 21 CFR 870.2345
Regulation Name: Electrocardiograph software for over-the-counter use.
Regulatory Class: Class II
Product Code: QDA
Dated: [NOTE: Use date of most recent supplement]
Received: June 13, 2025

Dear Aline Criton:

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,

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.*

510(k) Number *(if known)*
K240795

Device Name
Withings ECG App

Indications for Use *(Describe)*
The Withings ECG App is a software-only device intended for use with the ScanWatch to create, record, store, transfer and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The Withings ECG App determines the presence of atrial fibrillation (AFib), sinus rhythm and high heart rate (no signs of AFib with heart rate 100-150 bpm) on a classifiable waveform. The Withings ECG App is not recommended for users with other known arrhythmias.

The Withings ECG App is intended for over-the-counter (OTC) use. The ECG data displayed by the Withings ECG App is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without 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 not intended to replace traditional methods of diagnosis or treatment.

The Withings ECG App is intended to supplement rhythm classification for the purposes of discriminating AFib from normal rhythms. The device is not intended to replace traditional methods or diagnosis.

The ECG acquired by ScanWatch is not intended for manual and/or automated measurement of QT-interval.

The Withings ECG app is not intended for use by people under 22 years old.

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.**

# 510(k) Summary

## 1. Submitter

| | |
|---|---|
| 510(k) Number : | K240795 |
| Applicant: | Withings<br>2 Rue Maurice Hartmann<br>Issy-Les-Moulineaux<br>France 92130 |
| Submission Correspondent: | Aline Criton<br>Chief Clinical and Regulatory Affairs Officer<br>Phone: +33 6 64 20 47 65<br>Email: aline.criton@withings.com |
| Date Prepared: | June 13, 2025 |

## 2. Subject Device Information

| | |
|---|---|
| Device/Proprietary Name: | Withings ECG App |
| Classification/Regulation Name: | Electrocardiograph software for over-the-counter use |
| Regulation Number: | 21 CFR 870.2345 |
| Regulatory Class: | Class II |
| Product Code: | QDA |
| 510(k) review panel: | Cardiovascular |

## 3. Predicate Device Information

| | |
|---|---|
| Predicate Manufacturer: | Apple, Inc. |
| Predicate Device Name: | ECG 2.0 App |
| Predicate 510(k) Number: | K201525 |

## 4. Description of the Device

The Withings ECG App is a software only mobile medical application that has two components:

- Withings ECG Watch App
- Withings ECG Phone App

**Withings ECG Watch App**

The Withings ECG Watch App is integrated on the Withings ScanWatch, model number hwa10. The Withings ECG Watch App analyzes the data collected by electrodes on the Withings ScanWatch to generate an ECG waveform similar to a Lead I, calculate the average heart rate and provide rhythm classification to the user for a given 30 second session. Withings ECG Watch App uses machine learning techniques for ECG rhythm classification.

Withings ECG Watch App consists of a software library called **ECG-SW2 library**. The ECG-SW2, is a software library that includes an algorithm that processes the raw ECG signals and a tracing filter that filters the ECG signal to provide the user an output on the user interface (watch and smartphone).

**Withings ECG Phone App**

The Withings ECG Phone App contains the installation steps, tutorial and the instructions for use that the user must review prior to taking an ECG reading. The Withings ECG Phone App is included in the Withings App, which displays the ECG results and also allows the user to store, manage and share health data.

**5. Intended Use**

An electrocardiograph software device for over-the-counter use creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis.

**6. Indications for Use**

The Withings ECG App is a software-only device intended for use with the ScanWatch to create, record, store, transfer and display a single channel electrocardiogram (ECG) similar to a Lead I ECG. The Withings ECG App determines the presence of atrial fibrillation (AFib), sinus rhythm and high heart rate (no signs of AFib with heart rate 100-150 bpm) on a classifiable waveform. The Withings ECG App is not recommended for users with other known arrhythmias.

The Withings ECG App is intended for over-the-counter (OTC) use. The ECG data displayed by the Withings ECG App is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without 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 not intended to replace traditional methods of diagnosis or treatment.

The Withings ECG App is intended to supplement rhythm classification for the purposes of discriminating AFib from normal rhythms. The device is not intended to replace traditional methods or diagnosis.

The ECG acquired by ScanWatch is not intended for manual and/or automated measurement of QT-interval.

The Withings ECG app is not intended for use by people under 22 years old.

## 7. Comparison to the Predicate

| Characteristics | Subject device: Withings ECG App | Predicate device: ECG 2.0 App (K201525) | Comparison to predicate device |
|---|---|---|---|
| **Device Name** | Withings ECG App | ECG 2.0 App | NA |
| **Manufacturer** | Withings | Apple, Inc | NA |
| **510(k)** | Not assigned | K201525 | NA |
| **Regulation Number** | 21 CFR 870.2345 | 21 CFR 870.2345 | Identical |
| **Class** | Class II | Class II | Identical |
| **510(k) Review Panel** | Cardiovascular | Cardiovascular | Identical |
| **Product Code** | QDA | QDA | Identical |
| **Prescription / OTC** | OTC | OTC | Identical |
| **Intended use** | An electrocardiograph software device for over-the-counter use creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis. | An electrocardiograph software device for over-the-counter use creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis. | Substantially equivalent. Both the subject device and predicate have the same intended use. |

| | | | |
|---|---|---|---|
| **Indications for Use** | The Withings ECG App is a software-only device intended for use with the ScanWatch to create, record, store, transfer and display a single channel electrocardiogram (ECG) similar to a Lead I ECG.The Withings ECG app determines the presence of atrial fibrillation (AFib), sinus rhythm and high heart rate (no signs of AF with heart rate 100-150 bpm) on a classifiable waveform. The Withings ECG App is not recommended for users with other known arrhythmias.<br><br>The Withings ECG app is intended for over-the-counter (OTC) use. The ECG data displayed by the Withings ECG App is intended for informational use only. The user is not intended to interpret or take clinical action based on the device output without 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 not intended to replace traditional methods of diagnosis or treatment.<br><br>The ECG acquired by ScanWatch is not intended for manual and/or automated measurement of QT-interval.<br><br>The Withings ECG App is not intended for use by people under 22 years old. | 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). The ECG app is not recommended for users with other known arrhythmias.<br><br>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 based on the device output without 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 not intended to replace traditional methods of diagnosis or treatment.<br><br>The ECG app is not intended for use by people under 22 years old. | Substantially equivalent. Both the subject device and predicate have the same indications for use except for QT interval measurement. |
| **Clinical Application** | The Withings ECG App is intended to supplement rhythm classification for the purposes of discriminating Afib from normal rhythms. The device is not intended to replace traditional methods of diagnosis. | The ECG 2.0 app is intended to supplement rhythm classification for the purposes of discriminating Afib from normal rhythms. The device is not intended to replace traditional methods or diagnosis. | Substantially equivalent. Both the subject device and predicate have the same clinical application. |
| **Intended population** | Individuals (22 years or older) | Individuals (22 years or older) | Identical. |
| **ECG Channel** | Single Channel, Lead I | Single Channel, Lead I | Identical |
| **Prescription Use** | OTC | OTC | Identical |

**Table 1:** High-level comparison between the subject device and the predicate device for intended use and indications for use.

| Technological Characteristic | Subject device: Withings ECG App | Predicate device: ECG 2.0 App (K201525) | Comparison to predicate device |
|---|---|---|---|
| **Principle of Operation** | The Withings ECG App acquires platform sensor data from ScanWatch. After acquisition, the Withings ECG App algorithms process and classify the signal and display the classification to the user. | The ECG 2.0 app acquires platform sensor data from Apple Watch. After acquisition, the ECG 2.0 app algorithms process and classify the signal and display the classification to the user. | Substantially Equivalent. Both devices have the same principle of operation. Both devices acquire sensor data from a smartwatch, followed by algorithm processing, signal classification and ECG result display. |
| **Mechanism of Action** | The watch acquires the electrical potential between the electrode at the back of the watch and the bezel and generates an ECG waveform. | The watch acquires the electrical potential between the electrodes at the back of the watch and the digital crown and generates an ECG waveform. | Substantially Equivalent. The subject device uses the electrode from the back of the watch and the bezel whereas the predicate device uses electrodes at the back of the watch and the digital crown. However, the fundamental mechanism of action for both devices are the same. |
| **Use method** | While at rest, users complete a circuit with skin contact from two fingers on the smartwatch bezel while wearing the smartwatch on their wrist. The ECG recording session will last for 30 seconds. | While at rest, users complete a circuit with skin contact from a single finger on the digital crown while wearing the smartwatch on their wrist. The ECG recording session will last for 30 seconds. | Substantially Equivalent. Both devices follow a 30 second ECG recording session. For the subject device, the user is required to contact the bezel while wearing the watch on the wrist whereas for the predicate the user is required to touch the digital crown while wearing the watch on the wrist. This minor difference has been validated through human factors and usability testing and is in accordance with the special control requirement 4. |
| **Smartwatch Platform** | A single channel electrocardiogram (ECG) similar to a Lead I ECG taken from an electrode on the back of the watch and the bezel. | A single channel electrocardiogram (ECG) similar to a Lead I ECG taken from electrodes on the back of the watch and the digital crown. | Substantially Equivalent. Both devices have electrodes on a smartwatch with a single channel electrocardiogram (ECG) similar to a Lead I ECG. |
| **Anatomical sites** | Left hand fingers and right wrist or vice versa on a consumer grade electronic (smartwatch). | Left hand finger and right wrist or vice versa on a consumer grade electronic (smartwatch). | Substantially Equivalent. Both devices use finger(s) and wrist for ECG measurement. |
| **ECG Session Classification Results** | - Low Heart Rate (< 50 bpm)<br>- High Heart Rate (> 150 bpm)<br>- Sinus Rhythm (50-99 bpm)<br>- High Heart Rate (No AFib) (100-150 bpm) | - Low Heart Rate (< 50 bpm)<br>- High Heart Rate ( > 150 bpm)<br>- Sinus Rhythm (50-99 bpm)<br>- High Heart Rate (No AFib) (100-150 bpm) | Identical. |

| | | | |
|---|---|---|---|
| | - Atrial Fibrillation (50-99 bpm)<br>- Atrial Fibrillation High Heart Rate (50-150 bpm)<br>- Inconclusive<br>- Poor Recording | - Atrial Fibrillation (50-99 bpm)<br>- Atrial Fibrillation High Heart Rate (100-150 bpm)<br>- Inconclusive<br>- Poor Recording | |
| **User Interface** | Watch screen and mobile app screen | Watch screen and mobile app screen | Substantially equivalent. Both devices have similar user interfaces i.e. smartwatch and mobile app on a smartphone. |
| **ECG Waveform Display** | A single channel electrocardiogram (ECG) similar to a Lead I ECG | A single channel electrocardiogram (ECG) similar to a Lead I ECG | Substantially equivalent. Both devices display a single channel electrocardiogram (ECG) similar to a Lead I ECG. |
| **Compatibility** | ScanWatch model: hwa10 Withings App mobile application for Android and iOS smartphones. | Apple Watch (series 4 or later models)<br><br>Apple Health mobile application for iOS smartphones (iPhones) | Substantially equivalent. Both devices are compatible with a smartwatch and a mobile app on a smartphone. |

**Table 2:** High-level comparison between the subject device and the predicate device for technological characteristics and principle of operations.

The technological characteristics of the subject device and the predicate device are similar. Both devices are electrocardiograph software only devices for OTC (Over-the-counter) use that creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias. Both devices are not intended to provide a diagnosis.

Both are software only devices including an AFib detection algorithm. Both devices acquire platform sensor data from a smartwatch. The algorithm then processes and classifies the signal and displays the classification to the user. Therefore, both devices have the same principle of operation.

Both devices are compatible with a consumer grade electronic device (smartwatch). For the subject device, the watch acquires the electrical potential between the electrode at the back of the watch and the bezel whereas for the predicate device the watch acquires the electrical potential between the electrodes at the back of the watch and the digital crown. However, the fundamental mechanism of action for both the devices are the same.

The method of use for recording an ECG for the subject device involves fingers contacting the bezel and wrist contact with the back electrode of the watch whereas for the predicate it involves a finger contacting the digital crown and wrist contact with the back electrodes of the watch. This minor difference was assessed and tested through human factors and usability study, EC57 database testing and clinical testing.

In conclusion, the subject device and the predicate device have the same intended use and similar technological characteristics. Non-clinical testing and clinical testing demonstrate that the subject and predicate device have equivalent performance to determine 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. Therefore, the subject device, Withings ECG App is as safe and effective as the predicate device, ECG 2.0 App.

## 8. Summary of Performance Testing

### Nonclinical Testing

Both devices are software only devices, including the detection algorithm and its inputs and outputs. EC57 database testing was performed on the subject device to validate the algorithm.

Both devices use a consumer grade electronic device (smartwatch). Therefore all necessary non-clinical testing was performed on the platform (hardware) as aligned with the predicate device.

This testing included testing to the following standards:

- Input Signal Quality Testing per IEC 60601-2-47:2012 Medical Electrical Equipment – Ambulatory ECG Systems
- Applicable Radiofrequency and EMC requirements as listed below.
- Thermal and Electrical safety requirements under IEC 62368-1:2014
- ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R)2012 Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance,
- IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility Requirements And Tests, and
- IEC 60601-1-11: Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 62304:2006/Amd 1:2015 - Medical device software
- AAMI/ANSI/IEC 62366-1 : Medical Devices – Part 1: Application of Usability Engineering to Medical Devices : 2015
- Human Factors evaluation was conducted per FDA guidance document “Applying Human Factors and Usability Engineering to Medical Devices”
- ISO 14971 : Medical Devices – Application of Risk Management to Medical Devices
- AAMI TIR69:2017/(R2020) - Wireless coexistence
- ANSI IEEE C63.27-2017 - Wireless coexistence
- FCC testing per part 15

### Human Factors Testing

Human Factors Validation testing was performed on the Withings ECG App to demonstrate the device is safe and effective for the intended users, uses and use environments. Testing was conducted per FDA guidance, “Applying Human Factors and Usability Engineering to Medical Devices”.

The study included simulated use scenarios and knowledge task questions. During the interview process, objective and subjective data was collected to help determine potential

root causes of any use errors and difficulties related to the user interface. Participants were not given any formal training prior to using the Withings ECG App beyond the information provided in the Withings ECG App App tutorial and labeling.

Overall users were able to understand how to navigate and use the Withings ECG App, and were able to correctly interpret self-select whether using the app was appropriate for them and review the results and understand when it is appropriate to seek medical help. Users demonstrated a good level of understanding on the usage of the product.

Additionally, a separate self-selection study was conducted with non-intended users from the general public. Participants were given device labeling and tutorials to determine if they were an intended or non-intended user of the device. The study included simulated use scenarios and knowledge task questions. Participants were able to successfully self-select if they are an intended user of the Withings ECG App.

**ML algorithm training and testing**

The user datasets (Deep Train and Heartbeats) were used to run 4-Fold cross validations and act as train and test sets for hyperparameters tuning. Demographic information is summarized in Table 3.

| | **"Deep train"** (n=11701) | **"Heartbeats"** (n=5089) |
|---|---|---|
| Geography | European Union | United States |
| Race and Ethnicity | Not captured* | Not captured* |
| Sex | 73% male, 27% female | 76% male, 24% female |
| Mean age (std) | 59.2 (16.3) years | 51.3 (14.5) years |
| Mean BMI (std) | 27.3 (4.8) | 28.3 (5.6) |

**Table 3:** Demographic datasets used for training and testing of the ML algorithm.

* Due to GDPR regulations, servers are in Europe do not the right to hold users' race and ethnicity data

Three of the clinical study datasets (HWA08 test, HWA08 CE, WEFA HWA09 part 1) were used as a first layer of validation sets to verify that the models trained were capable of generalizing. A fourth dataset, WEFA HWA09 part 2, was used as a second layer of validation after the software freeze ("locked algorithm") to verify that the hyperparameters tuning were not overfit. Table 4 summarizes the demographic information of the 4 datasets.

| | **HWA08 test** (n=131) | **HWA08 CE** (n=137) | **WEFA HWA09 part 1** (n=162) | **WEFA HWA09 part 2** (n=100) |
|---|---|---|---|---|
| Age | Not Available | 66.6 (13.5) | 69.6 (13.6) | 65.2 (16.4) |
| Gender | | M: 59%, F: 41% | M: 64%, F: 36% | M: 56%, F: 44% |
| Demographics<br>Asian<br>African American<br>Caucasian<br>Other | | Not available | included in Other<br>9%<br>78%<br>13% | |
| BMI | | 27.8 (5.9) | 28.0 (6.1) | 26.7 (4.7) |
| Hypertension | | 43% | 49% | 56% |
| Dyslipidemia | | 21% | 35% | 33% |
| Overweight or obesity | | 55% | 43% | 41% |
| Diabetes | | 22% | 22% | 21% |
| VHD | | 9.5% | 22% | 10% |
| CAD | | 9.5% | 23% | 34% |
| HF | | 17.5% | 2% | 22% |
| MI, ischemic cardiopathy | | 7.3% | 5% | 23% |
| TIA or stroke | | 9.5% | 4% | 6% |
| POAD or AAA | | - | 4% | 16% |

**Table 4:** Demographic information of the datasets used for the pre-clinical validation of the ML algorithm.

### Clinical Testing

The Withings ECG App's ability to accurately classify an ECG recording into AFib and sinus rhythm was extensively tested in a pivotal, prospective, multi-center clinical trial of approximately 626 subjects - 219 were enrolled in the Atrial Fibrillation cohort, 369 were enrolled in the normal sinus rhythm cohort, 33 had other arrhythmias, and 5 were uninterpretable. The mean age of enrolled subjects was 64. Rhythm classification of a 12-lead ECG by a cardiologist was compared to the rhythm classification of a simultaneously collected ECG from the Withings ECG App. The Withings ECG App demonstrated 99.7% sensitivity in classifying AFib (HR 50-150 bpm) and 99.8% specificity in classifying sinus rhythm (HR 50-150 bpm) in classifiable recordings.

Subgroup analysis indicated sensitivity ranged from 99.0% - 100% across all age groups, and specificity ranged from 98.2% - 100%. Specificity and sensitivity estimates were

similar for females (100% and 99.6% respectively) and for males (99.5% and 100% respectively).

In addition, the morphology of the waveform was also tested in this clinical trial by visual assessment of the PQRST wave and R wave amplitude in comparison to a reference. The Withings ECG App produced visually acceptable PQRST waveforms with agreements on the visibilities of the waves as compared to a 12-lead reference ECG ranging from 95.3% for the P-waves to 100% for the QRS complexes and for the for T-waves, and agreements on the polarities ranging from 99.6% for T-waves to 100% for P-waves.

## 9. Conclusion

Withings ECG App (subject device) and ECG 2.0 App (predicate device) have the same intended use. Both devices are electrocardiograph software only devices for OTC (Over-the-counter) use that creates, analyzes, and displays electrocardiograph data, and can provide information for identifying cardiac arrhythmias.

The technological characteristics of the subject device and the predicate device are similar. Both are software only devices including an Afib detection algorithm. Both devices have the same principle of operation and mechanism of action. Both devices are compatible with a consumer grade electronic device (smartwatch). Non clinical testing and clinical testing demonstrate that the subject and predicate device have equivalent performance to determine 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.

Therefore, the subject device is as safe and effective as the predicate device and substantially equivalent.