

## **DE NOVO CLASSIFICATION REQUEST FOR ECG APP**

### **REGULATORY INFORMATION**

FDA identifies this generic type of device as:

**Electrocardiograph software for over-the-counter 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.

**NEW REGULATION NUMBER:** 21 CFR 870.2345

**CLASSIFICATION:** Class II

**PRODUCT CODE:** QDA

### **BACKGROUND**

**DEVICE NAME:** ECG App

**SUBMISSION NUMBER:** DEN180044

**DATE OF DE NOVO:** August 14, 2018

**CONTACT:** Apple Inc.  
One Apple Park Way  
Cupertino, CA 95014

### **INDICATIONS FOR USE**

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) or sinus rhythm 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 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 ECG app is not intended for use by people under 22 years old.

## **LIMITATIONS**

The device has only been evaluated for the detection of AFib or normal sinus rhythm and is not intended to detect any other type of arrhythmia. It cannot detect heart attacks. If you ever experience chest pain, pressure, tightness, or what you think is a heart attack, call emergency services.

Apple Watch may be unable to collect data when Apple Watch is in close vicinity to strong electromagnetic fields (e.g. electromagnetic anti-theft systems, metal detectors).

DO NOT wear your Apple Watch during a medical procedure (e.g., magnetic resonance imaging, diathermy, lithotripsy, cautery and external defibrillation procedures).

DO NOT change your medication without talking to your doctor.

Not intended for use by individuals under age 22.

Not intended for use by individuals previously diagnosed with AFib.

Notifications made by this feature are potential findings, not a complete diagnosis of cardiac conditions. All notifications should be reviewed by a medical professional for clinical decision-making.

Apple does not guarantee that you are not experiencing an arrhythmia or other health conditions even in the absence of an irregular rhythm notification. You should notify your physician if you experience any changes to your health.

The clinical study did not quantitatively assess the quality of the ECG waveform produced by the ECG App. The ECG produced by the ECG App is not intended for clinical use or as the basis for diagnosis or treatment. The ECG waveform is only intended for informational use.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

## **DEVICE DESCRIPTION**

The device (ECG App) comprises a pair of mobile medical apps — one on Apple Watch (the Watch App) and the other on the iPhone (iPhone App) — intended to record, store, transfer, and display a single lead ECG signal similar to a lead I. The ECG Watch App is intended to analyze this single lead data and detect the presence of atrial fibrillation (referred into this document as AFib or AF) and sinus rhythm in adults. It is also intended to acquire and analyze the single lead ECG recordings for display on the iPhone. The ECG iPhone App is included in the Health App, which is intended to store, manage, and share health and fitness data, and comes pre-installed on every iPhone.

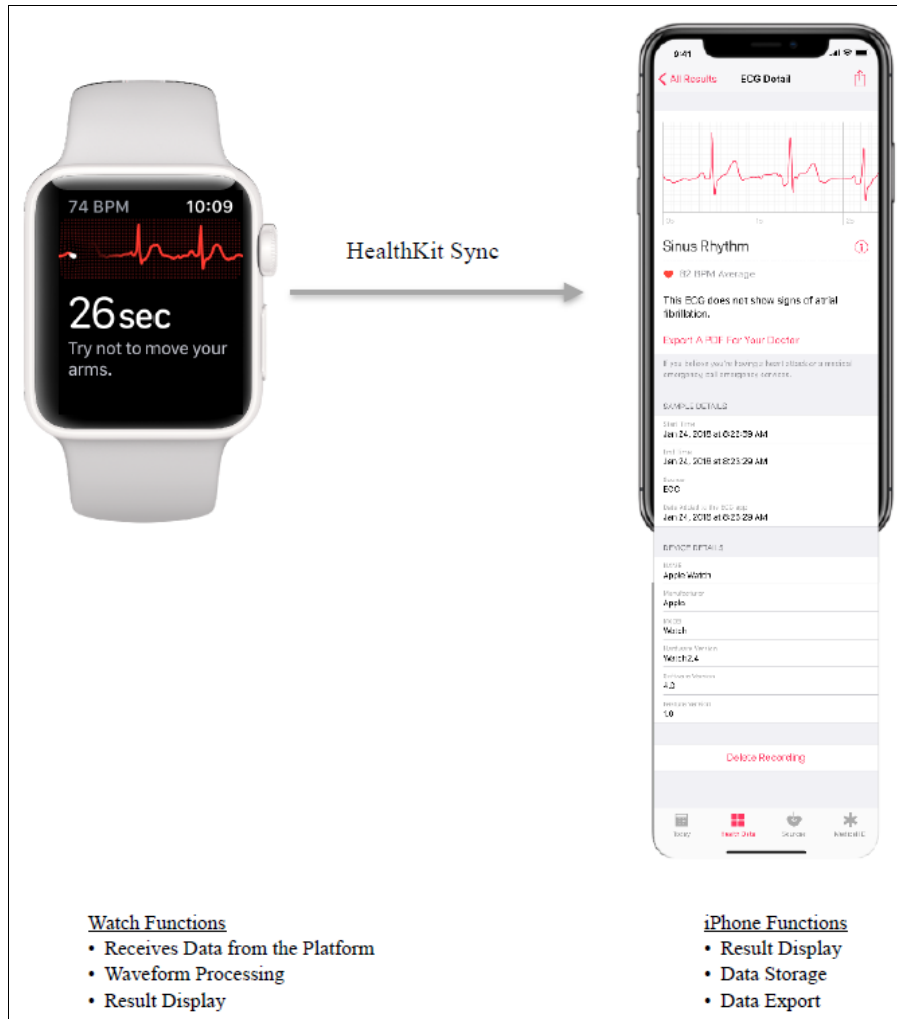


Figure 1: Apple Watch App and iPhone App components of the ECG App device

The ECG Watch App instructs the user to take an ECG measurement by holding their finger on the digital crown of the watch. The watch also contains electrodes on the back of the device which are in continuous contact with the user’s wrist. The watch acquires the electrical potential between the electrodes and digital crown. The Watch App will display a visual representation of the ECG waveform to provide information regarding signal quality during the session. The waveform displayed on the watch during the session is not intended for clinical purposes. The session will last for 30 seconds. Upon completion of the recording, the ECG Watch App analyzes the acquired ECG data and produces a waveform that is similar to a Lead I ECG for the purposes of AF and sinus rhythm evaluation, calculates average heart rate, and classifies the rhythm of the waveform (collectively called “session result”).

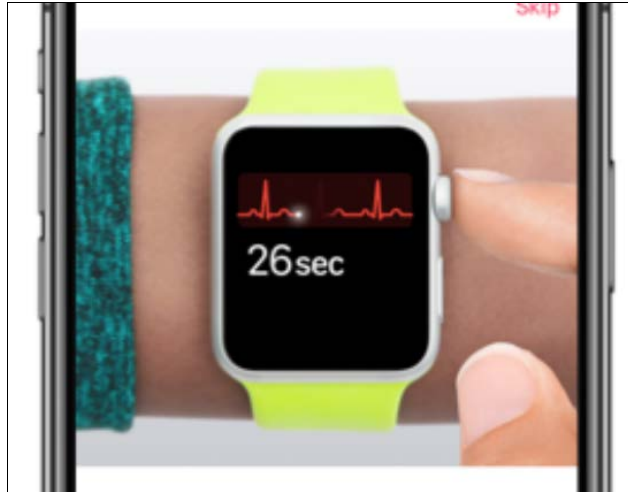


Figure 2: Taking a Measurement with the Digital Crown and the Watch App

The ECG rhythm will be classified into one of the following categories:

1. Sinus rhythm
2. Atrial Fibrillation
3. Inconclusive

There are two categories of Inconclusive rhythms: one for high heart rate, low heart rate or other arrhythmias; and one that is the result of poor signal quality and therefore unreadable by the algorithm.

#	UI Output	Definition	Algorithm Output
1	<p><b>Title: Sinus Rhythm</b></p> <p><u>Description:</u> This ECG does not show signs of Atrial Fibrillation.</p>	Regular rhythm with a HR between 50-100 bpm and less than 4 ectopic beats	regular_rhythm
2	<p><b>Title: Atrial Fibrillation</b></p> <p><u>Description:</u> This ECG shows signs of AFib.</p> <p>If this is an unexpected result, you should talk to your doctor.</p>	<p>AF with a HR between 50-100 bpm</p> <p>AF with a HR between 101-120 bpm</p>	<p>Afib</p> <p>Afib_HighHR</p>
3	<p><b>Title: Inconclusive</b></p> <p><u>Description:</u> Your ECG is inconclusive and will be saved.</p> <p>If you repeatedly get this result or you're not feeling well, you should talk to your doctor.</p>	<p>Regular rhythm with a HR greater than 100 bpm</p> <p>HR over 120</p> <p>HR under 50</p> <p>"Other" Rhythms: Rhythms other than AF or regular rhythm)</p>	<p>Unclassified_SinusTach</p> <p>Unclassified_HighHR</p> <p>Unclassified_LowHR</p> <p>Unclassified_other</p>
4	<p><b>Title: Inconclusive</b></p> <p><u>Description:</u> Your ECG is inconclusive due to a poor reading but will be saved.</p>	Poor Recording (e.g., noise, artifact, or poor signal quality)	Unreadable

Figure 3: ECG App analysis outputs

Once the ECG Watch App analyzes the ECG data, the Watch App displays the rhythm classification, average heart rate, and a description of the rhythm classification to the user on their Apple Watch. The session result is saved in Watch HealthKit and is then retrieved and stored in HealthKit on the paired iPhone.

Once the user sees the result of a given session on the Apple Watch App, the user will have the opportunity to pick from the following list of symptoms, which will be saved as part of the session result in Watch HealthKit:

- Rapid, pounding, or fluttering heartbeat
- Skipped heartbeat
- Fatigue
- Shortness of breath
- Chest tightness or pain
- Fainting
- Dizziness
- Other
- None

## SUMMARY OF NONCLINICAL/BENCH STUDIES

### EVALUATION OF INPUT SIGNAL QUALITY

To support the ability of the ECG App to obtain an ECG of sufficient quality for display and analysis, electromagnetic compatibility, electrical safety, and signal acquisition information was provided, in addition to clinical testing. Specifically, the Apple Watch claims conformance to EU and FCC compliance statements. The FCC listing includes all information needed for 47 CFR compliance. The Apple Watch conforms to EU standards EN 301 489-1 (V2.2.20), EN 301 489-3 (V2.1.1), EN 301 489-17 (V3.2.0), and EN 301 489-52 (V1.1.0). These standards were used as a comparator for IEC 60601-1-2, which is an FDA recognized consensus standard for medical device EMC. The following comparison data was submitted for the normative EMC standards referenced by EN 301 489-1 V2.2.20 and IEC 60601-1-2 (4<sup>th</sup> Edition):

- Radiated/Conducted Emissions
- Voltage Fluctuations and Flicker
- Harmonic Emissions
- Electrostatic Discharge
- Radiated Immunity and proximity fields
- Conducted Immunity
- Electrical Fast Transient/Burst
- Surge Immunity
- Voltage Dips/Interruptions
- Power Frequency Magnetic Fields
- Common Emitters

Electrical safety was assessed according to IEC 62368-1 (2014), “Audio/video, information and communication technology equipment – Part 1: Safety requirements.” Signal acquisition and platform (hardware) performance was assessed according to IEC 60601-2-47, “Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.” Platform performance testing included:

- Input differential range
- Input common-mode range
- ADC sampling rate
- ADC effective resolution
- Bandwidth
- Common-mode rejection
- Gain accuracy
- Linearity and dynamic range
- Input impedance
- System noise
- Frequency response
- Amplitude response
- Gain setting and stability
- Ambient temperature, humidity, and atmospheric pressure

**MAGNETIC RESONANCE (MR) COMPATIBILITY**

The device is not intended for use in an MR environment.

**SOFTWARE**

A failure or latent flaw in the ECG App could indirectly result in user injury; therefore, the software of this device is considered to have a “Moderate” level of concern. The submission contained all the elements of software documentation corresponding to the “Moderate” level of concern, as outlined in the FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” Documentation describing the software/firmware, software specifications, architecture design, software development environment, traceability, revision level history, unresolved anomalies, cybersecurity, and interoperability provide the foundation that the software will operate in a manner as described in the specifications. Hazard analysis was performed to characterize software risks including device malfunction and measurement related errors. The submission included verification and validation (V&V) testing to ensure that mitigation measures were successful.

**PERFORMANCE TESTING - BENCH**

**ECG Database Testing**

Testing to databases in EC57 was conducted for rhythms containing AF or normal sinus rhythm (NSR):

- (b) (4) records from the adjudicated AHA and MIT databases were used
- Each record was split into 30 second segments for a total of (b) (4)
- Assessed QRS detection, rhythm classification, and HR

The database annotations were used as ground truth. If a strip included any portion or period of AF derived from the annotations it was labeled as AF. Everything else was labeled not AF and used for assessing the false positive rate. The only exclusions from the TP/FP statistics were the (b) (4) ” by the algorithm (21 AF, (b) (4) Of the (b) (4) non-AF strips, (b) (4) were labeled as AF by the algorithm (false positives) and (b) (4) were true negatives (either sinus rhythm or inconclusive) (b) (4) of the available records were used for AF assessment.

Table 1: Database Testing Results

Algorithm Determination	Database Annotation		
	AF	NSR	Total
AF	(b) (4)	(b) (4)	(b) (4)
NSR	(b) (4)	(b) (4)	(b) (4)
Unread/Unclass	(b) (4)	(b) (4)	(b) (4)
Total	(b) (4)	(b) (4)	(b) (4)

(b) (4)

There were (b) (4) AF strips in database testing, of which:  
(b) (4) were “unreadable”  
(b) (4) were classified as NSR  
(b) (4) were “unclassified” (1 for being low HR)  
(b) (4) were classified as AF (b) (4) of readable strips)

### Human Factors

A Human Factors Validation Study was performed with a total of (b) (4) participants to demonstrate the usability of the user interface. The study enrolled (b) (4) user groups:

- Group 1 - Users diagnosed with AF (AF, n = 17)
- Group 2 - Users age 22-64 (Under 65, No AF, n = 17)
- Group 3 - Users age 65+ (Over 65, No AF, n = 16)

Each group included participants with and without smartphone experience as well as participants who use iPhone and Android.

Testing identified critical tasks as those tasks where the user does not understand the output from the device, or limitations of the device, and fails to seek medical care if there is a need based on the results from the app. Each task was assessed for completion and success criteria were clearly defined. Testing also collected subjective feedback in a written open response questionnaire and post-test interview.

### SUMMARY OF CLINICAL INFORMATION

A clinical study was performed to establish a reasonable assurance of safety and effectiveness of the ECG App.

#### **Methods**

The pivotal study was a prospective, parallel-cohort, non-randomized, multi-center, reader study using an enriched population. The study enrolled equal subjects with and without a known diagnosis of atrial fibrillation into two separate cohorts (AF Cohort and SR Cohort). Key exclusion criteria included antiarrhythmic drug use, the presence of a pacemaker or implantable cardioverter-defibrillator, and a history of abnormal life-threatening rhythms. Subjects in the SR cohort must not have any known diagnosis of AF. To be enrolled in the AF Cohort, the subject must be in atrial fibrillation at the time of enrollment.

Upon enrollment, the participant was coached on the appropriate posture and grip for acquiring an ECG recording using a prototype Apple Watch. After a 5-minute resting period, simultaneous 30-second ECG App and 12-lead ECG recordings were acquired. The ECG App rhythm strip was automatically classified by the algorithm as either “AF”, “SR”, “Unreadable”, or



“Unclassified.” Unclassified rhythms include any rhythms with rates  $> 120$  or  $< 50$  beats/min (bpm), regular rhythms with rates  $> 100$  bpm or more than 4 ectopic beats.

Three blinded independent board-certified cardiologists reviewed all ECG recordings and assigned a classification of SR, AF, unreadable, or others. Others classification was defined to include normal sinus with premature ventricular contraction (if  $\geq 4$  beats in the strip), normal sinus with PACS, 2nd degree block, AF with a rate  $> 120$  bpm, and supraventricular tachycardia. If the readers disagreed on the diagnosis, the final interpretation was determined by the simple majority rule.

In a subset of randomized selected subjects (Waveform Assessment Analysis Set), 3 independent certified cardiographic technicians synced and overlaid each ECG App rhythm strip with the Lead I strip of the corresponding 12-lead ECG. The first 6 consecutive distinct readable PQRST complexes were identified and used to determine if the morphology of the complexes appeared to overlay to the unaided eye. For the first two QRS complexes, the evaluators also measured and compared the R wave amplitude between the ECG App strip and the reference strip.

## **Study Endpoints**

### Primary Endpoint

Sensitivity and specificity of the ECG App algorithm in detecting AF compared with physician-adjudicated 12-lead ECG. The sensitivity and specificity performance goals were set at 90% and 92% respectively. Per the protocol, only readable and classifiable (Classifiable Analysis Set) paired recordings are included in the diagnostic performance assessment.

### Secondary Endpoint

The ECG app produces a waveform that provides clinically equivalent information to the gold standard (Lead I ECG). The following criteria assess the endpoint

1. Qualitative assessment  
The proportion of paired ECG strips appear to overlay to the unaided eye  $> 0.80$
2. Quantitative assessment  
The proportion of paired R-wave amplitude measurements within 2 mm of each other  $> 0.80$

## **Results**

### Subject characteristics

The study enrolled a total of 602 subjects at 5 investigational sites. Subject disposition is provided in Figure below. The study analysis excluded 14 subjects in the SR cohort due to a history of paroxysmal AF.

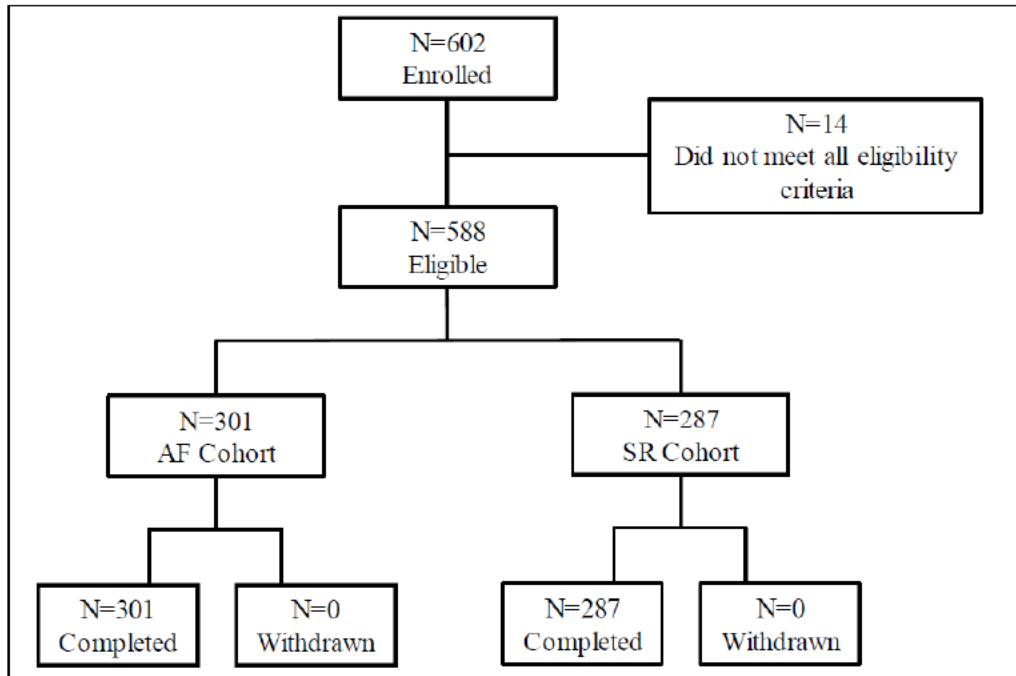


Figure 4: Flow Chart of Subject Disposition

The median age was 71 years, ranging from 22 to 92 years. Comparing to the SR cohort, subjects in the AF cohort were older (mean age 73.8 vs. 59.5) and less likely to be female (30.6% vs. 55.4%). Most AF subjects had a history of permanent AF (58.1%) or persistent AF (34.9%). A vast majority of SR subjects (87.5%) had no prior history of heart rhythm abnormalities, other rhythm abnormalities include Atrial Flutter (AFL) (n=1, 0.3%), Atrial Tachycardia (n=2, 0.7%), and first-degree AV block (n=15, 5.2%). Aside from AF, the most common concomitant conditions reported by enrolled subjects were hypertension (55.3%), hyperlipidemia (43.4%), and drug hypersensitivity (32.9%).

#### ECG App Automated AF Detection

The ECG App strip and reference 12 lead ECG Classifications were shown in the table below:

Table 2: ECG App and Reference Strip Classifications

ECG App Algorithm	Reference 12 Lead ECG Final Result				Total
	SR	AF	Other	Unreadable	
Sinus Rhythm	238	4	4	1	247
Atrial Fibrillation	1	236	2	2	241
Unclassified	6	7	6	0	19
Unreadable	18	30	1	0	49
Device Result Not Reported	32	13	1	0	46
<b>Total</b>	<b>295</b>	<b>290</b>	<b>14</b>	<b>3</b>	<b>602</b>

Of the 602 enrolled subjects who completed the study, 46 did not have an ECG App result. The reasons for ECG App result not reported are listed in the table below.

Table 3: Summary of ECG App Results Not Reported

Exclusion Criterion	Number of Subjects
Paroxysmal AF protocol deviation	14*
Data Interval < 30 Sec	1
Test Device Data Inverted	3
Fast Settle Switch Not Detected	12
Filename Cannot be Corrected	1
REF (reference) Data Inverted	8
Signals Not Aligned	2
Sync Not Detected	6*

\*One subject is included in both Paroxysmal AF protection deviation and Sync not detected.

The automated algorithm determined that the recording was unreadable or unclassified in 8.8% (N = 49) and 3.4% (N=19) respectively, and a diagnosis (i.e., SR, AF) was provided in 488 (87.8%) of the remaining 556 subjects.

Among the recordings where the algorithm output a diagnosis (Classifiable Analysis Set), AF was correctly diagnosed with 98.3% sensitivity (97.5% LCB: 95.8%) and 99.6% specificity (97.5% LCB: 97.7%). The results indicate that the study met the protocol specified primary endpoint.

Taking into account the unreadable and unclassified results, the probability that a subject with AF would receive an AF diagnosis from the ECG App was 85.2%.

Table 4: Summary of ECG App Performance when Unreadable and Unclassified Results Included

Performance	Probability
Pr (ECG App = SR   Reference = SR)	90.5% (95% CI: 86.3%, 93.8%)
Pr (ECG App = AF   Reference = AF)	85.2% (95% CI: 80.5%, 89.2%)

#### ECG App ECG Recording

A total of 139 (AF Cohort: 69, SR Cohort: 70) subjects were randomly selected to be included in the Waveform Assessment Analysis Set. Of these, 8 AF subjects and 5 SR subjects were excluded.

#### *Waveform Assessment*

Of the remaining 126 subjects, 125 (60 AF, 65 SR, 99.2%) subjects had an ECG App waveform that was considered to be clinically equivalent to the gold standard. The 97.5% LCB is 95.7%, which meets the secondary endpoint performance goal of 80% ( $p < 0.0001$ ).

#### *R Wave Amplitude*

The paired strips were examined for R-wave amplitude agreement. In 97.6% of subjects ( $n=123/126$ , 97.5% LCB: 93.2%), the paired R-Wave amplitude difference was  $\leq 2$  mm. The results meet the pre-specified PG of 80% ( $p < 0.0001$ ).

#### *Additional Analysis*

To further evaluate the quality of the ECG App recording, additional analysis (ad hoc) was performed comparing physician interpretation of the ECG App strips to the rhythm classification of the paired reference 12 lead ECGs. The results showed good concordance between the interpretation of the ECG App strip and the reference 12-lead ECG

Table 5: Cardiologist-interpretation of ECG App recordings vs. 12-lead ECG

	Reference Strip Read (US Board Certified Cardiologists)			
Manual Read of ECG App Strips	SR	AF	Unreadable	Total
SR	251	0	1	252
AF	0	243	1	244
Unreadable	10	24	1	35
Missing Data	41	30	0	71
Total	302	297	3	602

#### Safety

There were no adverse events reported by any subject in the study.

#### Pediatric Extrapolation

The device is indicated for use only in adults – that is, persons aged 22 and older. The Federal Food, Drug, and Cosmetic Act defines pediatric patients as persons aged 21 or younger. In this De Novo request, existing clinical data were not leveraged to support the use of the device in a pediatric patient population.

#### LABELING

The labeling for the device is sufficient and satisfies the requirements of 21 CFR 801 Subpart C for over-the-counter use. The labeling consists of Instructions for Use and an onboarding sequence for initial set-up. The Instructions for Use include the indications for use; a description of the device precautions; a detailed summary of the clinical data collected in support of the device; a list of potential adverse events; hardware and operating system compatibility requirements; guidance for interpretation of results; and instructions for the safe use of the device.

The ECG output of the device is limited to information use only. The qualitative nature of the Waveform Assessment could not determine if the ECG was sufficient for diagnostic use.

Please see the Limitations section above for important contraindications, warnings and precautions presented in the device labeling.

**RISKS TO HEALTH**

The table below identifies the risks to health that may be associated with use of electrocardiograph software for over-the-counter use:

Table 6: Identified Risks to Health and Mitigation Measures

<b>Identified Risks to Health</b>	<b>Mitigation Measures</b>
Poor quality ECG signal resulting in failure to detect arrhythmia	Clinical performance testing Human factors testing Labeling
Misinterpretation and/or over-reliance on device output, leading to: <ul style="list-style-type: none"> <li>• Failure to seek treatment despite acute symptoms</li> <li>• Discontinuing or modifying treatment for chronic heart condition</li> </ul>	Human factors testing Labeling
False negative resulting in failure to identify arrhythmia and delay of further evaluation or treatment	Clinical performance testing Software verification, validation, and hazard analysis Non-clinical performance testing
False positive resulting in additional unnecessary medical procedures	Clinical performance testing Software verification, validation, and hazard analysis Non-clinical performance testing Labeling

**SPECIAL CONTROLS**

In combination with the general controls of the FD&C Act, the electrocardiograph software for over-the-counter use is subject to the following special controls:

1. Clinical performance testing under anticipated conditions of use must demonstrate the following:
  - a. The ability to obtain an ECG of sufficient quality for display and analysis; and
  - b. The performance characteristics of the detection algorithm as reported by sensitivity and either specificity or positive predictive value.
2. Software verification, validation, and hazard analysis must be performed. Documentation must include a characterization of the technical specifications of the software, including the detection algorithm and its inputs and outputs.

3. Non-clinical performance testing must validate detection algorithm performance using a previously adjudicated data set.
4. Human factors and usability testing must demonstrate the following:
  - a. The user can correctly use the device based solely on reading the device labeling; and
  - b. The user can correctly interpret the device output and understand when to seek medical care.
5. Labeling must include:
  - a. Hardware platform and operating system requirements;
  - b. Situations in which the device may not operate at an expected performance level;
  - c. A summary of the clinical performance testing conducted with the device;
  - d. A description of what the device measures and outputs to the user; and
  - e. Guidance on interpretation of any results.

### **BENEFIT-RISK DETERMINATION**

The ECG App is intended to record a single-channel ECG and detect the presence of atrial fibrillation and regular rhythm. As an ambulatory single-lead ECG recorder, there are minimal safety concerns. The probable risks associated with using the ECG App are nearly all related to false results in AF detection or human use errors. False negative results may falsely reassure the user and cause delay or inappropriate changes in medical evaluation and treatment. A false positive result can lead to additional unnecessary medical procedures. In the clinical study, the false-positive and false-negative rates were 0.4% and 1.7% respectively when the device provided a rhythm classification. However, approximately 1 in 8 readings were inconclusive. There is also a risk of misinterpretation of the output by the user which can be compounded by false positive/negative results. However, this risk can be mitigated through labeling and requiring a human factors evaluation of whether users understand how the device output should be interpreted and when to seek further care from a physician.

The device provides the user a convenient and readily accessible means to record a 30-second single lead electrocardiogram (ECG) during the time of symptoms or unusual findings (e.g., irregular pulses). The ECG can then be reviewed by a medical professional to determine if the symptoms may be related to cardiac rhythm abnormalities. This is especially valuable for users with recurrent, transient but infrequent symptoms, which can be difficult to catch with traditional cardiac monitors. The information can be helpful to make the medical evaluation more efficient and obviate some unnecessary procedures.

In the clinical study, the device was accurate in discriminating AF from sinus rhythm. For users with undiagnosed AF, the device has the potential to provide early detection of the disease. Timely diagnosis of atrial fibrillation and consequent use of chronic oral anticoagulation in high risk patients can reduce the risk of stroke. Even in otherwise healthy users, atrial fibrillation may be the first manifestation of other diseases. In most cases, early detection and prompt treatment are likely to improve clinical outcomes.

Overall, the probable benefits outweigh the probable risks given the available information concerning the benefits and risks. There is reasonable assurance of the safety and effectiveness for this device for the intended use.

### Patient Perspectives

This submission did not include specific information on patient perspectives for this device.

### Benefit/Risk Conclusion

In conclusion, given the available information above, for the following indication statement:

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) or sinus rhythm 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 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 ECG app is not intended for use by people under 22 years old.

The probable benefits outweigh the probable risks for the ECG App. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

### CONCLUSION

The De Novo request for the ECG App is granted, and the device is classified under the following:

Product Code: QDA

Device Type: Electrocardiograph software for over-the-counter use

Class: II

Regulation Number: 21 CFR 870.2345