

K240795 Withings ECG AppJun 15, 2025
450 days to decisionK240795 · Product code: **QDA** · Cardiovascular
Source: <https://www.510kdatabase.net/k240795/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph Software For Over-the-counter Use (QDA)
Date received	Mar 22, 2024
Decision date	Jun 15, 2025
Days to decision	450 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Withings
Location	Hsin Chu City, TW
Contact	Khushboo Surendran
Website	http://www.withings.com
510(k) history	7 submissions · 7 cleared · 2011-2025

Withings is a digital health company that designs and manufactures connected medical devices for consumer health monitoring. The company develops smart scales, wearable watches, blood pressure monitors, and specialized health tracking devices. Withings operates with a manufacturing facility in Hsin Chu City, Taiwan. The company has received FDA 510(k) clearances from total submissions, with no denied submissions on record. Cardiovascular devices represent 71% of submissions, reflecting the company's core focus on heart health monitoring and blood pressure management. With...

CLINICAL EVIDENCE - NCT05316350**Withings ECG-app Study**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	685 patients (actual)
Study sites	10 sites
Condition studied	Atrial Fibrillation
Primary purpose	Basic_science
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Aug 15, 2023
Sponsor	Withings (Industry)

Primary outcome**Co-primary outcomes****Secondary outcome****Evaluation of the classification into heart rate subgroups**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05316350