

K252474 Withings BeamO (SCT02)

Nov 10, 2025
96 days to decision

K252474 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k252474/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrocardiograph (DPS) |
| Date received | Aug 6, 2025 |
| Decision date | Nov 10, 2025 |
| Days to decision | 96 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Withings |
| Location | Hsin Chu City, TW |
| Contact | Aline Criton |
| 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 - NCT06351761

WIBOFA - Validation of SCT02 With ECG-App for Detection of AF

| | |
|-------------------|---|
| Status | Completed - <i>No results published to ClinicalTrials.gov</i> |
| Enrollment | 373 patients (actual) |
| Study sites | 4 sites |
| Condition studied | Atrial Fibrillation |
| Primary purpose | Basic_science |
| Study type | Interventional |
| Study design | Parallel |
| Masking | Open label |
| Completion date | Nov 26, 2025 |
| Sponsor | Withings (Industry) |

Primary outcome

Co-primary outcome 1 - Sensitivity of Investigational Device

Secondary outcome

Rhythm classification by ranges of heart rate

Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT06351761