

**K201456 Scan Monitor**Oct 5, 2021  
491 days to decisionK201456 · Product code: **DPS** · Cardiovascular  
Source: <https://www.510kdatabase.net/k201456/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Jun 1, 2020
Decision date	Oct 5, 2021
Days to decision	491 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Withings SA</b>
Location	Issy-Les Moulineaux, FR
Contact	Debreuil Xavier
510(k) history	1 submissions · 1 cleared · 2021-2021

**CLINICAL EVIDENCE - NCT04351386**

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**Validation Study of the Watch HWA09 and Its Softwares ECG-SW1 and PPG-SW1 for the Detection of Atrial Fibrillation**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	283 patients (actual)
Study sites	3 sites
Condition studied	Atrial Fibrillation; Arrhythmia, Cardiac
Study type	Observational
Completion date	Apr 7, 2021
Sponsor	Withings (Industry)

**Primary outcome**

Sensitivity of the automatic classification in AF by ECG-SW1 of HWA09 single-lead ECG against reference 12-lead ECG

**Secondary outcome**

Sensitivity of the automatic classification in AF by PPG-SW1 of the HWA09 PPG against reference 12-lead ECG

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04351386](https://clinicaltrials.gov/study/NCT04351386)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201456/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov/)), ClinicalTrials.gov (U.S. National Library of Medicine).  
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