

K230812 Withings Scan Monitor 2.0Aug 23, 2023
152 days to decisionK230812 · Product code: **DPS** · Cardiovascular
Source: <https://www.510kdatabase.net/k230812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrocardiograph (DPS)
Date received	Mar 24, 2023
Decision date	Aug 23, 2023
Days to decision	152 days
Third-party review	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...
