

K110872 WITHINGS BLOOD PRESSURE MONITORMay 20, 2011
52 days to decisionK110872 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k110872/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Mar 29, 2011
Decision date	May 20, 2011
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Withings
Location	Hsin Chu City, TW
Contact	JEN KE-MIN
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...
