

**K160544 Withings Thermo (Model SCT01)**Jun 17, 2016  
112 days to decisionK160544 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k160544/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Feb 26, 2016
Decision date	Jun 17, 2016
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Withings</b>
Location	Hsin Chu City, TW
Contact	Xavier Debreuil
Website	<a href="http://www.withings.com">http://www.withings.com</a>
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...

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