

**K203215 Radius T wearable thermometer**Jun 11, 2021  
221 days to decisionK203215 · Product code: **FLL** · General Hospital  
Source: <https://www.510kdatabase.net/k203215/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Continuous Measurement Thermometer (FLL)
Date received	Nov 2, 2020
Decision date	Jun 11, 2021
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Masimo Corporation</b>
Location	Irvine, CA, US
Contact	Sindura Penubarthi
Website	<a href="http://www.masimo.com/">http://www.masimo.com/</a>
510(k) history	84 submissions · 82 cleared · 2004-2025

Masimo Corporation is an American health technology and consumer electronics company headquartered in Irvine, California. The company develops patient monitoring devices, non-invasive sensors, and related software platforms for hospital and home settings. Masimo has received FDA 510(k) clearances from total submissions since its first clearance in 2004. The company's regulatory focus centers on Anesthesiology devices, which represent 74% of submissions. Latest clearance activity in 2025 demonstrates continued regulatory engagement. Recent cleared devices span Anesthesiolo...

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Device record: <https://www.510kdatabase.net/k203215/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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