

**K243727 Re:Balans**Oct 16, 2025  
317 days to decisionK243727 · Product code: **DSB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k243727/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plethysmograph, Impedance (DSB)
Date received	Dec 3, 2024
Decision date	Oct 16, 2025
Days to decision	317 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mode Sensors AS</b>
Location	Trondheim, NO
Contact	Magnus Nordahl
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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