

**K241037 ABL90 FLEX PLUS System**Jan 14, 2025  
273 days to decisionK241037 · Product code: **CEM** · Chemistry  
Source: <https://www.510kdatabase.net/k241037/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Potassium (CEM)
Date received	Apr 16, 2024
Decision date	Jan 14, 2025
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Radiometer Medicals Aps</b>
Location	Brønshøj, DK
Contact	Andrea Swingle
Website	<a href="https://www.radiometer.com">https://www.radiometer.com</a>
510(k) history	5 submissions · 5 cleared · 2024-2026

Radiometer Medicals Aps is a global provider of acute care testing solutions with a manufacturing facility in Brønshøj, Denmark. The company specializes in blood gas analyzers, immunoassay testing, and point-of-care diagnostic systems for hospitals and clinical laboratories. Radiometer has received FDA 510(k) clearances from total submissions, with all submissions focused on Chemistry devices. The company's first FDA clearance was in 2024, with the most recent clearance in 2026, demonstrating continued regulatory activity and product innovation in acute care diagnostics. ...

**CLINICAL EVIDENCE - NCT05804487****ABL90 FLEX PLUS Clinical Precision Study for 15 Parameters in Adult Whole Blood**

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Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	100 patients (actual)
Study sites	1 site
Condition studied	Diagnostic Test
Study type	Observational
Completion date	Aug 31, 2023
Sponsor	Radiometer Medical ApS (Industry)

**Primary outcome**

Repeatability (SD) in whole blood for each parameter, measuring mode and parameter level, pooled across sites.

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT05804487](https://clinicaltrials.gov/study/NCT05804487)

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