

**K252488 ABL90 FLEX PLUS System**May 1, 2026  
266 days to decisionK252488 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k252488/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Aug 8, 2025
Decision date	May 1, 2026
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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. ...