

K252207 ABL90 FLEX PLUS System, safeCLINITUBES

Apr 10, 2026
270 days to decision

K252207 · Product code: **CHL** · Chemistry
Source: <https://www.510kdatabase.net/k252207/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Jul 14, 2025
Decision date	Apr 10, 2026
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Radiometer Medicals Aps
Location	Brønshøj, DK
Contact	Andrea Swingle
Website	https://www.radiometer.com
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. ...