

K253491 ISE indirect K for Gen.2Feb 12, 2026
111 days to decisionK253491 · Product code: **CEM** · Chemistry
Source: <https://www.510kdatabase.net/k253491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Potassium (CEM)
Date received	Oct 24, 2025
Decision date	Feb 12, 2026
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ISE indirect Na for Gen.2; ISE indirect Cl for Gen.2; cobas pro integrated solutions

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	Noel Mencias
Website	https://diagnostics.roche.com
510(k) history	182 submissions · 180 cleared · 2005-2026

Roche Diagnostics is a Swiss multinational healthcare company specializing in diagnostic devices and solutions. The company operates its U.S. diagnostics division from Indianapolis. Roche Diagnostics maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 2005. The company's portfolio spans chemistry devices, immunology assays, microbiology testing, and hematology systems. The latest clearance in 2026 reflects continued innovation and regulatory engagement. Recent cleared devices include glucose monitoring systems, elec...