

K230890 ISE ElectrodesSep 8, 2023
161 days to decisionK230890 · Product code: **CEM** · Chemistry
Source: <https://www.510kdatabase.net/k230890/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Ion Specific, Potassium (CEM)
Date received	Mar 31, 2023
Decision date	Sep 8, 2023
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Randox Laboratories, Ltd.
Location	Antrim, N. Ireland, IR
Contact	Karena Shaw
Website	http://www.randox.com/
510(k) history	116 submissions · 115 cleared · 1992-2025

Randox Laboratories, Ltd. is a global diagnostic company specializing in chemistry devices and laboratory solutions. The company operates with a manufacturing facility in Antrim, Northern Ireland, and has over 40 years of expertise in diagnostic innovation. Randox has received FDA 510(k) clearances from total submissions since its first clearance in 1992. The company's regulatory portfolio is dominated by chemistry devices, including clinical chemistry analyzers, reagents, controls, and electrodes. The latest clearance on record dates to 2023. Recent FDA 510(k) cleared de...