

**K200544 SmartLyte® Plus Electrolyte Analyzer
Na+/K+/Cl-/Ca++/Li+**Oct 1, 2020
212 days to decisionK200544 · Product code: **CEM** · Chemistry
Source: <https://www.510kdatabase.net/k200544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Potassium (CEM)
Date received	Mar 3, 2020
Decision date	Oct 1, 2020
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diamond Diagnostics, Inc.
Location	Holliston, MA, US
Contact	Kathy Fisher
510(k) history	26 submissions · 26 cleared · 2001-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200544/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 15, 2026