

**K112995 GEM PREMIER 4000**May 3, 2012  
209 days to decisionK112995 · Product code: **CEM** · Chemistry  
Source: <https://www.510kdatabase.net/k112995/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Potassium (CEM)
Date received	Oct 7, 2011
Decision date	May 3, 2012
Days to decision	209 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Instrumentation Laboratory CO</b>
Location	Mchenry, IL, US
Contact	CARL MARBLE
510(k) history	321 submissions · 320 cleared · 1976-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112995/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 15, 2026