

**K173403 GEM Premier 5000**Dec 29, 2017  
59 days to decisionK173403 · Product code: **CHL** · Chemistry  
Source: <https://www.510kdatabase.net/k173403/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode Measurement, Blood-gases (pco2, Po2) And Blood Ph (CHL)
Date received	Oct 31, 2017
Decision date	Dec 29, 2017
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173403/> 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 May 31, 2026