

**K961335 GEM PREMIER PLUS MODEL 5500**Jun 28, 1996  
81 days to decisionK961335 · Product code: **CHL** · Chemistry  
Source: <https://www.510kdatabase.net/k961335/>**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	Apr 8, 1996
Decision date	Jun 28, 1996
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mallinckrodt Sensor Systems, Inc.</b>
Location	Ann Arbor, MI, US
Contact	ANDREW C TAYLOR
510(k) history	2 submissions · 2 cleared · 1991-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961335/> 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 30, 2026