

**K111143 POLY-CHEM 90 TOTAL BILIRUBIN**Sep 1, 2011  
132 days to decisionK111143 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k111143/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Apr 22, 2011
Decision date	Sep 1, 2011
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Polymedco, Inc.</b>
Location	Cortlandt Manor, NY, US
Contact	HELEN LANDICHO
510(k) history	19 submissions · 19 cleared · 1992-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111143/> 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 18, 2026