

**K082210 TOTAL BILIRUBIN L3K, MODEL 295-10 AND 295-30**Dec 16, 2008  
132 days to decisionK082210 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k082210/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Aug 6, 2008
Decision date	Dec 16, 2008
Days to decision	132 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Genzyme Diagnostics P.E.I., Inc.</b>
Location	Charlottetown, Prin Ed Island, CA
Contact	PENNY J WHITE
510(k) history	2 submissions · 2 cleared · 2008-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082210/> 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 23, 2026