

**K003693 DIRECT BILIRUBIN**Jan 29, 2001  
60 days to decisionK003693 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k003693/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Nov 30, 2000
Decision date	Jan 29, 2001
Days to decision	60 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Jas Diagnostics, Inc.</b>
Location	Miami, FL, US
Contact	DAVID JOHNSON
510(k) history	20 submissions · 20 cleared · 2000-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003693/> 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 7, 2026