

**K963909 HEMOCUE GLUCOLIN**Nov 8, 1996  
39 days to decisionK963909 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k963909/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 30, 1996
Decision date	Nov 8, 1996
Days to decision	39 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Direct Solutions</b>
Location	Westford, MA, US
Contact	BILL DONOHUE
510(k) history	5 submissions · 5 cleared · 1995-1996

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963909/> 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 28, 2026