

**K103450 FDI GLUCOSE CONTROL SOLUTION FOR FREESTYLE**Jan 25, 2011  
62 days to decisionK103450 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k103450/>**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	Nov 24, 2010
Decision date	Jan 25, 2011
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujirebio Diagnostics,Inc.</b>
Location	North Caldwell, NJ, US
Contact	KENT PRUETT
510(k) history	45 submissions · 43 cleared · 1989-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103450/> 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 19, 2026