

**K102260 FDI GLUCOSE CONTROL SOLUTIONS**Sep 24, 2010  
45 days to decisionK102260 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k102260/>**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	Aug 10, 2010
Decision date	Sep 24, 2010
Days to decision	45 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/k102260/> 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 20, 2026