

**K133197 FDI LEVEL I AND LEVEL II GLUCOSE CONTROLS FOR THE EMBRACE NO CODE**

Jan 17, 2014  
92 days to decision

K133197 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k133197/>

**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	Oct 17, 2013
Decision date	Jan 17, 2014
Days to decision	92 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/k133197/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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