

K092645 FDI GLUCOSE CONTROL LEVELS 1, 2 AND 3Sep 5, 2009
9 days to decisionK092645 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k092645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Aug 27, 2009
Decision date	Sep 5, 2009
Days to decision	9 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujirebio Diagnostics,Inc.
Location	North Caldwell, NJ, US
Contact	JOHN GORMLEY
510(k) history	45 submissions · 43 cleared · 1989-2025

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