

K110436 FDI GLUCOSE CONTROL SOLUTION FOR AVIVAApr 20, 2011
64 days to decisionK110436 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k110436/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Feb 15, 2011
Decision date	Apr 20, 2011
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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