

K081915 FDTX GLUCOSE CONTROL SOLUTIONAug 8, 2008
36 days to decisionK081915 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k081915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jul 3, 2008
Decision date	Aug 8, 2008
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujirebio Diagnostics Texas, Inc.
Location	Seguin, TX, US
Contact	JOHN GORMLEY
510(k) history	2 submissions · 2 cleared · 2008-2008

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