

K080273 AB-TROL AND PRIVATE LABEL GLUCOSE CONTROL SOLUTIONAug 8, 2008
189 days to decisionK080273 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k080273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Feb 1, 2008
Decision date	Aug 8, 2008
Days to decision	189 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080273/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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