

**K123612 FDI GLUCOSE CONTROL SOLUTION FOR USE WITH ACCU-CHEK AVIVA**

Jan 17, 2013  
55 days to decision

K123612 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k123612/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Nov 23, 2012
Decision date	Jan 17, 2013
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k123612/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026