

**K123851 GLUCOSE METER-CHECK SOLUTION FOR ROCHE
ACCU-CHEK**Feb 14, 2013
62 days to decisionK123851 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k123851/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Dec 14, 2012
Decision date	Feb 14, 2013
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionostics, Inc.
Location	Mchenry, IL, US
Contact	RANDY BYRD
510(k) history	49 submissions · 49 cleared · 1983-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123851/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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