

**K081403 GLUCOSE METER-CHECK CONTROL SOLUTION FOR
ROCHE ACCU-CHEK**Jul 25, 2008
67 days to decisionK081403 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k081403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	May 19, 2008
Decision date	Jul 25, 2008
Days to decision	67 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/k081403/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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