

**K112356 GLUCOSE METER-CHECK CONTROL SOLUTION FOR
AGAMATRIX WAVESENSE**Sep 19, 2011
34 days to decisionK112356 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k112356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Aug 16, 2011
Decision date	Sep 19, 2011
Days to decision	34 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/k112356/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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