

**K112352 GLUCOSE METER-CHECK CONTROL FOR NIPRO
TRUERESULT**Dec 23, 2011
129 days to decisionK112352 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k112352/>**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	Dec 23, 2011
Days to decision	129 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/k112352/> 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 8, 2026