

K091914 OMNIS HEALTH EMBRACE GLUCOSE CONTROL SOLUTIONNov 6, 2009
129 days to decisionK091914 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k091914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jun 30, 2009
Decision date	Nov 6, 2009
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091914/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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