

**K050100 RNA1C HEMOGLOBIN A1C CONTROL FOR BAYER
DCA2000 AND DCA2000+ ANALYZER**Feb 25, 2005
38 days to decisionK050100 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k050100/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jan 18, 2005
Decision date	Feb 25, 2005
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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