

**K050961 RNA1C CONTROL FOR NYCOCARD HBA1C**May 13, 2005  
25 days to decisionK050961 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k050961/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Apr 18, 2005
Decision date	May 13, 2005
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bionostics, Inc.</b>
Location	Mchenry, IL, US
Contact	KATHLEEN STORRO
510(k) history	49 submissions · 49 cleared · 1983-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050961/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026