

**K082395 GLUCOSE METER-CHECK CONTROL SOLUTION FOR BAYER ASCENSIA BLOOD GLUCOSE METER, MODEL: MC002**

Sep 18, 2008  
30 days to decision

K082395 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k082395/>

**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	Aug 19, 2008
Decision date	Sep 18, 2008
Days to decision	30 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/k082395/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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