

**K953097 OPUS T4 CONTROLS**Aug 24, 1995  
52 days to decisionK953097 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k953097/>**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	Jul 3, 1995
Decision date	Aug 24, 1995
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Behring Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	NANCY M JOHANSEN
510(k) history	145 submissions · 145 cleared · 1976-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953097/> 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 28, 2026