

**K033379 BAYER SPECIAL CHEMISTRY CONTROLS**Dec 19, 2003  
58 days to decisionK033379 · Product code: **JJY** · Chemistry  
Source: <https://www.510kdatabase.net/k033379/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Oct 22, 2003
Decision date	Dec 19, 2003
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bayer Diagnostics Corp.</b>
Location	Medfield, MA, US
Contact	ANDRES HOLLE
510(k) history	32 submissions · 32 cleared · 2000-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033379/> 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