

K033380 BAYER SPECIAL CHEMISTRY CALIBRATORSDec 16, 2003
55 days to decisionK033380 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k033380/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Multi-analyte Mixture (JIX)
Date received	Oct 22, 2003
Decision date	Dec 16, 2003
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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