

**K033643 CO2 CALIBRATOR/DILUENT**Jan 8, 2004  
49 days to decisionK033643 · Product code: **JIT** · Chemistry  
Source: <https://www.510kdatabase.net/k033643/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Nov 20, 2003
Decision date	Jan 8, 2004
Days to decision	49 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bayer Healthcare, Diagnostics Division</b>
Location	New York, NY, US
Contact	KENNETH T EDDS, PH.D.
510(k) history	2 submissions · 2 cleared · 2004-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033643/> 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 29, 2026