

**K031775 PRECISET DAT PLUS I CALIBRATORS**Aug 5, 2003  
56 days to decisionK031775 · Product code: **DKB** · Chemistry  
Source: <https://www.510kdatabase.net/k031775/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Jun 10, 2003
Decision date	Aug 5, 2003
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	KERWIN KAUFMAN
510(k) history	264 submissions · 263 cleared · 1999-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031775/> 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 9, 2026