

**K031856 PRECISET TDM I AND PRECISET TDM II  
CALIBRATORS**Aug 6, 2003  
51 days to decisionK031856 · Product code: **DKB** · Toxicology  
Source: <https://www.510kdatabase.net/k031856/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Jun 16, 2003
Decision date	Aug 6, 2003
Days to decision	51 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/k031856/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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