

K033306 PRECISET DAT PLUS II AND CFAS DAT QUALITATIVE PLUS CALIBRATORSDec 15, 2003
62 days to decisionK033306 · Product code: **DKB** · Chemistry
Source: <https://www.510kdatabase.net/k033306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Oct 14, 2003
Decision date	Dec 15, 2003
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033306/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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