

**K060645 PRECISET DAT PLUS I, PRECISET DAT PLUS II AND
CFAS DAT QUALITATIVE PLUS CALIBRATORS**May 30, 2006
81 days to decisionK060645 · Product code: **DKB** · Toxicology
Source: <https://www.510kdatabase.net/k060645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrators, Drug Mixture (DKB)
Date received	Mar 10, 2006
Decision date	May 30, 2006
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k060645/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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