

K033165 PRECISET DAT AMPHETAMINE CALIBRATORSOct 14, 2003
14 days to decisionK033165 · Product code: **DLJ** · Chemistry
Source: <https://www.510kdatabase.net/k033165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Sep 30, 2003
Decision date	Oct 14, 2003
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary
Other names	CFAS DAT QUALITATIVE AMPHETAMINE CALIBRATORS

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k033165/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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