

K080183 CONTROL SET DAT I, CONTRL SET DAT II, CONTROL SET DAT III, CONTROL SET AMPHETAMINE 1000 AND CONTROL SET AMPHETAMINE 500Mar 25, 2008
60 days to decisionK080183 · Product code: **DIF** · Chemistry
Source: <https://www.510kdatabase.net/k080183/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Drug Mixture Control Materials (DIF)
Date received	Jan 25, 2008
Decision date	Mar 25, 2008
Days to decision	60 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

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