

K061093 CHOLINESTERASE GEN.2 TEST SYSTEMJul 3, 2006
75 days to decisionK061093 · Product code: **DIH** · Toxicology
Source: <https://www.510kdatabase.net/k061093/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetry, Cholinesterase (DIH)
Date received	Apr 19, 2006
Decision date	Jul 3, 2006
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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