

K043576 ROCHE AMPLICHIP CYP450 TESTJan 10, 2005
14 days to decisionK043576 · Product code: **NTI** · Chemistry
Source: <https://www.510kdatabase.net/k043576/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Metabolizing Enzyme Genotyping Systems (NTI)
Date received	Dec 27, 2004
Decision date	Jan 10, 2005
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Molecular Systems, Inc.
Location	Somerville, NJ, US
Contact	JAMES F KELLY
510(k) history	51 submissions · 48 cleared · 1993-2026

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