

K013757 ROCHE ACETAMINOPHENJan 8, 2002
56 days to decisionK013757 · Product code: **LDP** · Toxicology
Source: <https://www.510kdatabase.net/k013757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetry, Acetaminophen (LDP)
Date received	Nov 13, 2001
Decision date	Jan 8, 2002
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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