

K043303 ONLINE DAT PROPOXYPHENE PLUSMar 11, 2005
101 days to decisionK043303 · Product code: **JXN** · Toxicology
Source: <https://www.510kdatabase.net/k043303/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Propoxyphene (JXN)
Date received	Nov 30, 2004
Decision date	Mar 11, 2005
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

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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