

K983174 ONTRAK TESTSTIK FOR BARBITURATES, ONTRAK TESTSTIK FOR BENZODIAZEPINESNov 18, 1998
69 days to decisionK983174 · Product code: **JXM** · Toxicology
Source: <https://www.510kdatabase.net/k983174/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Benzodiazepine (JXM)
Date received	Sep 10, 1998
Decision date	Nov 18, 1998
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	MARIA FEIJOO
510(k) history	296 submissions · 296 cleared · 1983-1999

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