

K031902 ONLINE TDM CARBAMAZEPINESep 17, 2003
89 days to decisionK031902 · Product code: **KLT** · Toxicology
Source: <https://www.510kdatabase.net/k031902/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Jun 20, 2003
Decision date	Sep 17, 2003
Days to decision	89 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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