

**K010814 EMIT 2000 CARBAMAZEPINE ASSAY, MODEL
OSR4F229**Apr 13, 2001
25 days to decisionK010814 · Product code: **KLT** · Toxicology
Source: <https://www.510kdatabase.net/k010814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Mar 19, 2001
Decision date	Apr 13, 2001
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Syva Co., Dade Behring, Inc.
Location	San Jose, CA, US
Contact	VIRGINIA SINGER
510(k) history	19 submissions · 19 cleared · 2000-2001

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