

K993028 ABBOTT AEROSOL CARBAMAZEPINE ASSAY AND CALIBRATORSJan 27, 2000
140 days to decisionK993028 · Product code: **KLT** · Toxicology
Source: <https://www.510kdatabase.net/k993028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Sep 9, 1999
Decision date	Jan 27, 2000
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary
Other names	MODELS 1E12 AND 6E90

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	PAUL L ROGERS
510(k) history	448 submissions · 447 cleared · 1976-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993028/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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