

K853835 EMIT QST CARBAMAZEPINE ASSAYOct 1, 1985
15 days to decisionK853835 · Product code: **KLT** · Toxicology
Source: <https://www.510kdatabase.net/k853835/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Sep 16, 1985
Decision date	Oct 1, 1985
Days to decision	15 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

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

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