

**K973535 ACE CARBAMAZEPINE REAGENT/AED
CALIBRATORS**

Oct 20, 1997
32 days to decision

K973535 · Product code: **KLT** · Chemistry
Source: <https://www.510kdatabase.net/k973535/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Sep 18, 1997
Decision date	Oct 20, 1997
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Schiapparelli Biosystems, Inc.
Location	Fairfield, NJ, US
Contact	STEVEN DALESSIO
510(k) history	24 submissions · 24 cleared · 1993-1999

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Device record: <https://www.510kdatabase.net/k973535/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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