

**K962820 CARBAMAZEPINE FLEX REAGENT CARTRIDGE**Sep 13, 1996  
56 days to decisionK962820 · Product code: **KLT** · Toxicology  
Source: <https://www.510kdatabase.net/k962820/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Jul 19, 1996
Decision date	Sep 13, 1996
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dade Intl., Inc.</b>
Location	Deerfield, IL, US
Contact	CAROLYN K GEORGE
510(k) history	30 submissions · 30 cleared · 1995-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962820/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026