

**K955100 CARBAMAZEPINE EIA TEST**Dec 13, 1995  
35 days to decisionK955100 · Product code: **KLT** · Toxicology  
Source: <https://www.510kdatabase.net/k955100/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Nov 8, 1995
Decision date	Dec 13, 1995
Days to decision	35 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Diagnostic Reagents, Inc.</b>
Location	Walker, MI, US
Contact	YUH-GENG TSAY
510(k) history	66 submissions · 66 cleared · 1982-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k955100/> 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