

**K893507 INNOFLUOR CARBAMAZEPINE REAGENT SET**Aug 11, 1989  
98 days to decisionK893507 · Product code: **KLT** · Chemistry  
Source: <https://www.510kdatabase.net/k893507/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	May 5, 1989
Decision date	Aug 11, 1989
Days to decision	98 days
Third-party review	No

**APPLICANT**

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Company	<b>Innotron of Oregon, Inc.</b>
Location	Mchenry, IL, US
Contact	JANELLE BATLEY
510(k) history	28 submissions · 28 cleared · 1980-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k893507/>; 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 29, 2026