

**K940374 QMS CARBAMAZEPINE ASSAY**Jun 2, 1994  
127 days to decisionK940374 · Product code: **KLT** · Toxicology  
Source: <https://www.510kdatabase.net/k940374/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Jan 26, 1994
Decision date	Jun 2, 1994
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Seradyn, Inc.</b>
Location	Indianapolis, IN, US
Contact	ANDRIS INDRIKSONS, PH.D.
510(k) history	28 submissions · 28 cleared · 1988-2007

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940374/> 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