

**K894519 FPR CARBAMAZEPINE KIT**Aug 28, 1989  
39 days to decisionK894519 · Product code: **KLT** · Toxicology  
Source: <https://www.510kdatabase.net/k894519/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Jul 20, 1989
Decision date	Aug 28, 1989
Days to decision	39 days
Third-party review	No

**APPLICANT**

---

Company	<b>Colony Laboratories, Inc.</b>
Location	Washington, DC, US
Contact	DALE B HINSON
510(k) history	16 submissions · 16 cleared · 1989-1989

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894519/>; 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