

K894520 FPR CARBAMAZEPINE CALIBRATOR KITAug 28, 1989
39 days to decisionK894520 · Product code: **DLJ** · Toxicology
Source: <https://www.510kdatabase.net/k894520/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Jul 20, 1989
Decision date	Aug 28, 1989
Days to decision	39 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k894520/>, Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026