

**K895568 PRIMIDONE (FPIA) CALIBRATOR KIT**Sep 28, 1989  
22 days to decisionK895568 · Product code: **DLJ** · Toxicology  
Source: <https://www.510kdatabase.net/k895568/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrators, Drug Specific (DLJ)
Date received	Sep 6, 1989
Decision date	Sep 28, 1989
Days to decision	22 days
Third-party review	No

**APPLICANT**

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Company	<b>Tudor Laboratories, Inc.</b>
Location	Dallas, TX, US
Contact	DOWBEN, MD
510(k) history	9 submissions · 9 cleared · 1989-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895568/>; 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