

K943711 EZ-SCREEN:PCPSep 9, 1994
39 days to decisionK943711 · Product code: **LCM** · Toxicology
Source: <https://www.510kdatabase.net/k943711/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phencyclidine (LCM)
Date received	Aug 1, 1994
Decision date	Sep 9, 1994
Days to decision	39 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Editek, Inc.
Location	Burlington, NC, US
Contact	CAROLE GOLDEN
510(k) history	7 submissions · 7 cleared · 1994-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943711/> 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 28, 2026