

K934061 BIOTRACK VALPROIC ACID TEST CARTRIDGEDec 29, 1993
132 days to decisionK934061 · Product code: **LEG** · Toxicology
Source: <https://www.510kdatabase.net/k934061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Valproic Acid (LEG)
Date received	Aug 19, 1993
Decision date	Dec 29, 1993
Days to decision	132 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Biotrack, Inc.
Location	Sunnyvale, CA, US
Contact	BERNELLE SAPERSTEIN
510(k) history	16 submissions · 16 cleared · 1986-1993

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934061/> 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