

K901538 MODIFIED OPUS VALPROIC ACID TEST SYSTEMJun 26, 1990
85 days to decisionK901538 · Product code: **LEG** · Toxicology
Source: <https://www.510kdatabase.net/k901538/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Valproic Acid (LEG) |
| Date received | Apr 2, 1990 |
| Decision date | Jun 26, 1990 |
| Days to decision | 85 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Pb Diagnostic Systems, Inc. |
| Location | Westwood, MA, US |
| Contact | LORI BARANAUSKAS |
| 510(k) history | 35 submissions · 35 cleared · 1988-1994 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k901538/>; 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