

K895569 VALPROIC ACID (FPIA) KITOct 3, 1989
27 days to decisionK895569 · Product code: **LEG** · Toxicology
Source: <https://www.510kdatabase.net/k895569/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Valproic Acid (LEG) |
| Date received | Sep 6, 1989 |
| Decision date | Oct 3, 1989 |
| Days to decision | 27 days |
| Third-party review | No |

APPLICANT

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

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