

K891581 COBAS-FP REAGENT FOR VALPROIC ACID & CALIBRATORSAug 15, 1989
148 days to decisionK891581 · Product code: **LEG** · Toxicology
Source: <https://www.510kdatabase.net/k891581/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Enzyme Immunoassay, Valproic Acid (LEG) |
| Date received | Mar 20, 1989 |
| Decision date | Aug 15, 1989 |
| Days to decision | 148 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |

APPLICANT

| | |
|----------------|---|
| Company | Roche Diagnostic Systems, Inc. |
| Location | Mchenry, IL, US |
| Contact | ALEX WESOLOWSKI |
| 510(k) history | 296 submissions · 296 cleared · 1983-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k891581/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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