

K002551 EMIT 2000 VALPROIC ACID ASSAY, EMIT 2000 VALPROIC ACID CALIBRATORS, MODEL 4G019UL, 4G109UL

Oct 11, 2000
55 days to decision

K002551 · Product code: **LEG** · Chemistry
Source: <https://www.510kdatabase.net/k002551/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Valproic Acid (LEG)
Date received	Aug 17, 2000
Decision date	Oct 11, 2000
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	PAUL L ROGERS
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k002551/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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