

K984232 MODIFICATION OF EMIT D.A.U. OPIATES ASSAYJan 22, 1999
58 days to decisionK984232 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k984232/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Nov 25, 1998
Decision date	Jan 22, 1999
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Syva Co.
Location	Mchenry, IL, US
Contact	PAUL L ROGERS
510(k) history	448 submissions · 447 cleared · 1976-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k984232/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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