

K935117 EMIT(R) IIC OPIATE ASSAYJan 6, 1994
71 days to decisionK935117 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k935117/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Oct 27, 1993
Decision date	Jan 6, 1994
Days to decision	71 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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