

K011289 EMIT II PLUS OPIATE ASSAY, MODEL OSR9B229May 15, 2001
18 days to decisionK011289 · Product code: **DJG** · Toxicology
Source: <https://www.510kdatabase.net/k011289/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Apr 27, 2001
Decision date	May 15, 2001
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Syva Co., Dade Behring, Inc.
Location	San Jose, CA, US
Contact	SUSAN COLLINS
510(k) history	19 submissions · 19 cleared · 2000-2001

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