

**K011164 MODIFICATION TO THE EMIT II PLUS
METHAQUALONE ASSAY, MODEL OSR9Q229**May 10, 2001
24 days to decisionK011164 · Product code: **KXS** · Toxicology
Source: <https://www.510kdatabase.net/k011164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Radioimmunoassay, Methaqualone (KXS)
Date received	Apr 16, 2001
Decision date	May 10, 2001
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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