

**K011166 MODIFICATION TO EMIT 2000 THEOPHYLLINE
ASSAY, MODEL OSR 4P229**May 10, 2001
24 days to decisionK011166 · Product code: **KLS** · Chemistry
Source: <https://www.510kdatabase.net/k011166/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Theophylline (KLS)
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	VIRGINIA SINGER
510(k) history	19 submissions · 19 cleared · 2000-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011166/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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