

K913123 EMIT(R) 2000 THEOPHYLLINE ASSAY/CALIBRATORSSep 19, 1991
66 days to decisionK913123 · Product code: **KLS** · Toxicology
Source: <https://www.510kdatabase.net/k913123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Jul 15, 1991
Decision date	Sep 19, 1991
Days to decision	66 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

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