

K972495 ACCUMETER THEOPHYLLINE TESTOct 10, 1997
99 days to decisionK972495 · Product code: **KLS** · Toxicology
Source: <https://www.510kdatabase.net/k972495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Jul 3, 1997
Decision date	Oct 10, 1997
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chemtrak, Inc.
Location	Sunnyvale, CA, US
Contact	SUBBARAO GUNUPUDI
510(k) history	7 submissions · 7 cleared · 1991-1997

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