

**K973583 ACE THEOPHYLLINE REAGENT, THEO  
CALIBRATORS**

Nov 12, 1997  
51 days to decision

K973583 · Product code: **KLS** · Toxicology  
Source: <https://www.510kdatabase.net/k973583/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Sep 22, 1997
Decision date	Nov 12, 1997
Days to decision	51 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Schiapparelli Biosystems, Inc.</b>
Location	Fairfield, NJ, US
Contact	STEVEN DALESSIO
510(k) history	24 submissions · 24 cleared · 1993-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k973583/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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