

**K834244 THEOFAST TEST KIT FOR QUANTITATIVE THEO**Jan 24, 1984  
48 days to decisionK834244 · Product code: **KLS** · Toxicology  
Source: <https://www.510kdatabase.net/k834244/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Dec 7, 1983
Decision date	Jan 24, 1984
Days to decision	48 days
Third-party review	No

**APPLICANT**

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Company	<b>Allergenetics</b>
Location	Walker, MI, US
510(k) history	8 submissions · 8 cleared · 1982-1985

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k834244/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026