

**K952596 THEOPHYLLINE ENZYME IMMUNOASSAY**Aug 11, 1995  
66 days to decisionK952596 · Product code: **KLS** · Toxicology  
Source: <https://www.510kdatabase.net/k952596/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Jun 6, 1995
Decision date	Aug 11, 1995
Days to decision	66 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Diagnostic Reagents, Inc.</b>
Location	Walker, MI, US
Contact	YUH-GENG TSAY
510(k) history	66 submissions · 66 cleared · 1982-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k952596/> 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 28, 2026