

**K891761 GDS ENZYMATIC THEOPHYLLINE REAGENT**May 16, 1989  
53 days to decisionK891761 · Product code: **LCY** · Chemistry  
Source: <https://www.510kdatabase.net/k891761/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	U.v. Spectrometry, Theophylline (LCY)
Date received	Mar 24, 1989
Decision date	May 16, 1989
Days to decision	53 days
Third-party review	No

**APPLICANT**

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Company	<b>Gds Diagnostics</b>
Location	Elkhart, IN, US
Contact	DE CASTRO
510(k) history	4 submissions · 4 cleared · 1989-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k891761/>, 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