

**K863475 THEOFAST(TM) TEST PACKAGE**Nov 5, 1986  
57 days to decisionK863475 · Product code: **LER** · Chemistry  
Source: <https://www.510kdatabase.net/k863475/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Theophylline (LER)
Date received	Sep 9, 1986
Decision date	Nov 5, 1986
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

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Company	<b>3M Company</b>
Location	White City, OR, US
Contact	ALEXANDER A MONTE
Website	<a href="http://www.3m.com/">http://www.3m.com/</a>
510(k) history	331 submissions · 322 cleared · 1976-2025

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