

K961462 CEDIA THEOPHYLLINE ASSAYJun 27, 1996
71 days to decisionK961462 · Product code: **KLS** · Toxicology
Source: <https://www.510kdatabase.net/k961462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Apr 17, 1996
Decision date	Jun 27, 1996
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boehringer Mannheim Corp.
Location	Mchenry, IL, US
Contact	BETSY SOARES-MADDOX
510(k) history	340 submissions · 340 cleared · 1976-1999

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