

K812518 AMES TDA THEOPHYLLINE TESTSep 23, 1981
21 days to decisionK812518 · Product code: **LER** · Chemistry
Source: <https://www.510kdatabase.net/k812518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Theophylline (LER)
Date received	Sep 2, 1981
Decision date	Sep 23, 1981
Days to decision	21 days
Third-party review	No

APPLICANT

Company	Miles Laboratories, Inc.
Location	Mchenry, IL, US
510(k) history	158 submissions · 158 cleared · 1976-1988

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k812518/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026