

K810943 AMES TDA THEOPHYLLINE TESTApr 17, 1981
10 days to decisionK810943 · Product code: LER · Toxicology
Source: <https://www.510kdatabase.net/k810943/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Theophylline (LER)
Date received	Apr 7, 1981
Decision date	Apr 17, 1981
Days to decision	10 days
Third-party review	No

APPLICANT

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

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