FDA 510(k) Premarket Notification

K800646 AMES TDA THEOPHYL-LINE TEST

CLEARED

Apr 10, 1980
17 days to decision

K800646 · Product code: **KLS** · Toxicology
Source: https://www.510kdatabase.net/k800646/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Mar 24, 1980
Decision date	Apr 10, 1980
Days to decision	17 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.net
Device record: https://www.510kdatabase.net/k800646/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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