

K801736 AMES TDA TM PHENYTOIN TESTAug 20, 1980
26 days to decisionK801736 · Product code: **LES** · Toxicology
Source: <https://www.510kdatabase.net/k801736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Immunoassay, Diphenylhydantoin (LES)
Date received	Jul 25, 1980
Decision date	Aug 20, 1980
Days to decision	26 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/k801736/> 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