

K803107 AMES TDA AMIKACIN CONTROL SERUMDec 22, 1980
12 days to decisionK803107 · Product code: **LAS** · Chemistry
Source: <https://www.510kdatabase.net/k803107/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Specific Control Materials (LAS)
Date received	Dec 10, 1980
Decision date	Dec 22, 1980
Days to decision	12 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/k803107/> 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