

K063492 VITEK 2 GRAM POSITIVE ERYTHROMYCIN FOR STREPTOCOCCUS PNEUMONIAE

Dec 21, 2006
34 days to decision

K063492 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k063492/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Nov 17, 2006
Decision date	Dec 21, 2006
Days to decision	34 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	JOHN TENLLADO
510(k) history	251 submissions · 250 cleared · 1983-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k063492/> 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 June 28, 2026