

**K063623 VITEK 2 GRAM POSITIVE MEROPENEM FOR
STREPTOCOCCUS PNEUMONIAE**Jan 11, 2007
36 days to decisionK063623 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k063623/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Dec 6, 2006
Decision date	Jan 11, 2007
Days to decision	36 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063623/> 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