

**K063597 VITEK 2 GRAM POSITIVE AMOXICILLIN FOR  
STREPTOCOCCUS PNEUMONIAE**Jan 19, 2007  
46 days to decisionK063597 · Product code: **LON** · Microbiology  
Source: <https://www.510kdatabase.net/k063597/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Dec 4, 2006
Decision date	Jan 19, 2007
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063597/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026