

K091126 VITEK 2 GRAM POSITIVE DAPTOMYCINJun 18, 2009
59 days to decisionK091126 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k091126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Apr 20, 2009
Decision date	Jun 18, 2009
Days to decision	59 days
Third-party review	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/k091126/> 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 22, 2026