FDA 510(k) Premarket Notification

CLEARED

K260282 VITEK 2 AST-Streptococcus Inducible Clindamycin Resistance

Apr 15, 2026
76 days to decision

K260282 · Product code: **LON** · Microbiology
Source: https://www.510kdatabase.net/k260282/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Jan 29, 2026
Decision date	Apr 15, 2026
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

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