

K212243 VITEK 2 AST- Gram Positive Telavancin (≤ 0.015 - ≥ 1 $\mu\text{g/mL}$)Aug 8, 2022
385 days to decisionK212243 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k212243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Jul 19, 2021
Decision date	Aug 8, 2022
Days to decision	385 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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