

K212849 VITEK 2 AST-Gram Positive Linezolid ($\leq 0.5 - \geq 8$ $\mu\text{g/mL}$)Feb 4, 2022
150 days to decisionK212849 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k212849/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Sep 7, 2021
Decision date	Feb 4, 2022
Days to decision	150 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biom?rieux, Inc.
Location	Hazelwood, MO, US
Contact	Esther Hernandez
510(k) history	1 submissions · 1 cleared · 2022-2022

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