

K234000 VITEK 2 AST-Gram Positive Lefamulin (≤ 0.03 - ≥ 4 $\mu\text{g/mL}$)Mar 11, 2024
84 days to decisionK234000 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k234000/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Dec 18, 2023
Decision date	Mar 11, 2024
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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