

**K222378 VITEK 2 AST-Gram Negative Levofloxacin (≤ 0.125
 $\rightarrow \leq 8$ ug/mL)**Jun 26, 2023
325 days to decisionK222378 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k222378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Aug 5, 2022
Decision date	Jun 26, 2023
Days to decision	325 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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