

K223478 VITEK® 2 AST-Gram Negative Plazomicin (=0.5 - =16 µg/mL)Feb 16, 2023
90 days to decisionK223478 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k223478/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Nov 18, 2022
Decision date	Feb 16, 2023
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VITEK® 2 AST-GN Plazomicin (=0.5 - =16 µg/mL); VITEK® 2 AST-GN Plazomicin

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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