

K222430 VITEK 2 AST-Gram Negative Fosfomycin (<=4 - >=256 µg/mL), VITEK 2 AST-GN Fosfomycin (<=4 - >=256 µg/mL), VITEK 2 AST-GN Fosfomycin

Mar 9, 2023
210 days to decision

K222430 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k222430/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Aug 11, 2022
Decision date	Mar 9, 2023
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux Sa, Inc.
Location	Hazelwood, MO, US
Contact	Craig Buehler
510(k) history	1 submissions · 1 cleared · 2023-2023

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Device record: <https://www.510kdatabase.net/k222430/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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