

K230864 VITEK 2 AST-Gram Positive Daptomycin (<=0.12 - >=8 µg/mL), VITEK 2 AST-GP Daptomycin (<=0.12 - >=8 µg/mL), VITEK 2 AST-GP Daptomycin

Jul 5, 2023
98 days to decision

K230864 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k230864/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Mar 29, 2023
Decision date	Jul 5, 2023
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k230864/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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