

K220805 VITEK 2 AST-Gram Positive Cefoxitin ScreenOct 13, 2022
209 days to decisionK220805 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k220805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Mar 18, 2022
Decision date	Oct 13, 2022
Days to decision	209 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220805/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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