CLEARED

K220803 VITEK 2 AST-Gram Positive Moxifloxacin (=0.25 - =8 µg/ml), VITEK 2 AST-GP Moxifloxacin (=0.25 - =8 µg/mL), VITEK 2 AST-GP Moxifloxacin

Jan 27, 2023
315 days to decision

K220803 · Product code: **LON** · Microbiology
Source: https://www.510kdatabase.net/k220803/

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	Jan 27, 2023
Days to decision	315 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**bioMerieux, Inc.**
Location	Mchenry, IL, US
Contact	Cherece L. Jones
510(k) history	251 submissions · 250 cleared · 1983-2026