

K200590 VITEK 2 AST-Gram Positive Delafloxacin (≤ 0.015 - ≥ 1 $\mu\text{g/mL}$)Apr 28, 2020
53 days to decisionK200590 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k200590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Mar 6, 2020
Decision date	Apr 28, 2020
Days to decision	53 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200590/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026