

K181766 VITEK 2 AST-Gram Positive Inducible Clindamycin ResistanceDec 10, 2018
160 days to decisionK181766 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k181766/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Jul 3, 2018
Decision date	Dec 10, 2018
Days to decision	160 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/k181766/> 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