

K161227 VITEK 2 AST-GN Cefepime (<=0.12->=32 ug/mL)Jul 20, 2016
79 days to decisionK161227 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k161227/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	May 2, 2016
Decision date	Jul 20, 2016
Days to decision	79 days
Third-party review	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/k161227/> 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 2, 2026