

K041982 VITEK 2 GRAM NEGATIVE ERTAPENEMSep 14, 2004
53 days to decisionK041982 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k041982/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Jul 23, 2004
Decision date	Sep 14, 2004
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	Nancy Weaver
510(k) history	251 submissions · 250 cleared · 1983-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041982/> 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