

K072038 VITEK 2 GRAM NEGATIVE LEVOFLOXACINSep 12, 2007
49 days to decisionK072038 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k072038/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Jul 25, 2007
Decision date	Sep 12, 2007
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	JOLYN TENLIADO
510(k) history	251 submissions · 250 cleared · 1983-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k072038/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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