

K031865 VITEK 2 GRAM POSITIVE MOXIFLOXACIN FOR STREPTOCOCCUS PNEUMONIAEAug 13, 2003
57 days to decisionK031865 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k031865/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Jun 17, 2003
Decision date	Aug 13, 2003
Days to decision	57 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

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