

K181368 VITEK 2 AST-YS Micafungin (<=0.06 - =>8 µg/mL)Jun 20, 2018
28 days to decisionK181368 · Product code: **NGZ** · Microbiology
Source: <https://www.510kdatabase.net/k181368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Susceptibility Test Plate, Antifungal (NGZ)
Date received	May 23, 2018
Decision date	Jun 20, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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