

K232963 VITEK 2 AST-Yeast Anidulafungin (<= 0.015 - >= 8 µg/mL)Jun 7, 2024
260 days to decisionK232963 · Product code: **NGZ** · Microbiology
Source: <https://www.510kdatabase.net/k232963/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Plate, Antifungal (NGZ)
Date received	Sep 21, 2023
Decision date	Jun 7, 2024
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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