

K061945 VITEK 2 AST-YS FLUCONAZOLESep 19, 2006
71 days to decisionK061945 · Product code: **NGZ** · Microbiology
Source: <https://www.510kdatabase.net/k061945/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Plate, Antifungal (NGZ)
Date received	Jul 10, 2006
Decision date	Sep 19, 2006
Days to decision	71 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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