

K211539 Sensititre YeastOne Susceptibility System with Voriconazole in the dilution range of 0.008 - 8 ug/mL

Dec 15, 2021
211 days to decisionK211539 · Product code: **NGZ** · Microbiology
Source: <https://www.510kdatabase.net/k211539/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Plate, Antifungal (NGZ)
Date received	May 18, 2021
Decision date	Dec 15, 2021
Days to decision	211 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Thermo Fisher Scientific
Location	Noble Park, AU
Contact	Cynthia Knapp
Website	http://www.thermofisher.com/
510(k) history	64 submissions · 64 cleared · 2007-2025

Thermo Fisher Scientific is a global life science and clinical research company based in Waltham, Massachusetts. The company operates a facility in Noble Park, Australia, providing scientific consumables, equipment, and services worldwide. Thermo Fisher has received FDA 510(k) clearances from total submissions since 2007. The company specializes primarily in Microbiology devices, which represent 89% of its regulatory submissions. Recent clearances include multiple Sensititre susceptibility systems for antimicrobial testing. The latest FDA 510(k) clearance was granted in 2...

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