

K191167 Fungitell STATJul 17, 2019
77 days to decisionK191167 · Product code: **NQZ** · Microbiology
Source: <https://www.510kdatabase.net/k191167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Invasive Fungal Pathogens (NQZ)
Date received	May 1, 2019
Decision date	Jul 17, 2019
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Associates of Cape Cod, Inc.
Location	Woodbury, MN, US
Contact	Alison Skinner
510(k) history	2 submissions · 1 cleared · 2004-2019

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