

K151817 VITEK 2 AST-YS Caspofungin ≤ 0.125 - ≥ 8 ug/mLFeb 18, 2016
227 days to decisionK151817 · Product code: **NGZ** · Microbiology
Source: <https://www.510kdatabase.net/k151817/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Susceptibility Test Plate, Antifungal (NGZ) |
| Date received | Jul 6, 2015 |
| Decision date | Feb 18, 2016 |
| Days to decision | 227 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151817/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 3, 2026