

**K250856 ETEST Aztreonam/Avibactam (AZA) (0.016/4-256/4
µg/mL)**Jun 12, 2025
83 days to decisionK250856 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k250856/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Mar 21, 2025
Decision date	Jun 12, 2025
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Biom?rieux
Location	Marcy-L'toile, FR
Contact	Stéphanie Millon-Serme
510(k) history	2 submissions · 2 cleared · 2023-2025

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