

**K250274 ETEST Imipenem/Relebactam P. aeruginosa (IRPA)
(0.008/4-128/4 µg/mL)**Apr 30, 2025
90 days to decisionK250274 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k250274/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Jan 30, 2025
Decision date	Apr 30, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Biomerieux S.A.
Location	Craponne, FR
Contact	Sophie Quiblier
510(k) history	16 submissions · 16 cleared · 2011-2025

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