

**K232395 ETEST® Sulbactam/Durlobactam (SUD) (0.004/4-64/4 µg/mL), ETEST® SUD**Oct 5, 2023  
57 days to decisionK232395 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k232395/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Aug 9, 2023
Decision date	Oct 5, 2023
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biom?rieux</b>
Location	Marcy-L&apos;toile, FR
Contact	Sophie Quiblier
510(k) history	2 submissions · 2 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232395/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026