

**K251580 MTS Sulbactam-Durlobactam 0.004/4 - 64/4 µg/mL
(SUD)**Aug 20, 2025
89 days to decisionK251580 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k251580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	May 23, 2025
Decision date	Aug 20, 2025
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Liofilchem S. R. L.
Location	Abruzzi, IT
Contact	Fabio Rocco
510(k) history	35 submissions · 35 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	Laboratory Specialists, Inc.
Contact	Laura Koeth

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251580/> 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 May 14, 2026