

**K252114 MTS Aztreonam-Avibactam 0.016/4 - 256/4 µg/mL**Oct 2, 2025  
87 days to decisionK252114 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k252114/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Jul 7, 2025
Decision date	Oct 2, 2025
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Laboratory Specialists, Inc.</b>
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)

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