

**K192345 MTS Ampicillin-Sulbactam 0.016/0.008 - 256/128 µg/mL**Oct 31, 2019  
63 days to decisionK192345 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k192345/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Aug 29, 2019
Decision date	Oct 31, 2019
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Laboratory Specialists, Inc.</b>
Contact	Anne R. Windau

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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