

**K182557 MTS Eravacycline 0.002 - 32 µg/mL**Nov 2, 2018  
46 days to decisionK182557 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k182557/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Sep 17, 2018
Decision date	Nov 2, 2018
Days to decision	46 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	Laura M. 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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