

**K183527 MTS Ciprofloxacin 0.002 - 32 µg/mL**Mar 19, 2019  
90 days to decisionK183527 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k183527/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Dec 19, 2018
Decision date	Mar 19, 2019
Days to decision	90 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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