

**K183140 MTS Tetracycline 0.016 - 256 ug/mL**Jan 11, 2019  
59 days to decisionK183140 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k183140/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Nov 13, 2018
Decision date	Jan 11, 2019
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

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)

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183140/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026