

K182922 MTS Omadacycline 0.002-32 µg/mLDec 14, 2018
56 days to decisionK182922 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k182922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Oct 19, 2018
Decision date	Dec 14, 2018
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Laboratory Specialists, Inc.
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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