

K200308 MTS Lefamulin 0.016- 256 µg/mLApr 6, 2020
60 days to decisionK200308 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k200308/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Feb 6, 2020
Decision date	Apr 6, 2020
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Liofilchem S. R. 1.
Location	Roseto Degli Abruzzi, IT
Contact	Fabio Brocco
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Laboratory Specialists, Inc.
Contact	Anne R Windau

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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