

K191809 MTS Imipenem-relebactam 0.002/4-32/4 µg/mLAug 23, 2019
49 days to decisionK191809 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k191809/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Jul 5, 2019
Decision date	Aug 23, 2019
Days to decision	49 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	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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