

K230479 ComASP Cefiderocol 0.008-128May 18, 2023
85 days to decisionK230479 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k230479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Feb 22, 2023
Decision date	May 18, 2023
Days to decision	85 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 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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