

K251879 Sulopenem SPM 2 µgAug 12, 2025
55 days to decisionK251879 · Product code: **JTN** · Microbiology
Source: <https://www.510kdatabase.net/k251879/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Jun 18, 2025
Decision date	Aug 12, 2025
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Statement

APPLICANT

Company	Liofilchem
Location	Waltham, MA, US
Contact	Emily Hodgkins
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251879/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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