

K250885 Ceftobiprole BPR 5 µg DiscJun 23, 2025
90 days to decisionK250885 · Product code: JTN · Microbiology
Source: <https://www.510kdatabase.net/k250885/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Mar 25, 2025
Decision date	Jun 23, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Statement

APPLICANT

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

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