

K261853 Gepotidacin GEP 10 µg

Jul 23, 2026
50 days to decision

K261853 · Product code: JTN · Microbiology
Source: <https://www.510kdatabase.net/k261853/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Jun 3, 2026
Decision date	Jul 23, 2026
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Liofilchem, Inc.
Location	Waltham, MA, US
Contact	Emily Hodgkins
510(k) history	2 submissions · 2 cleared · 2025-2026