

**K260696 MTS Gepotidacin 0.016-256 µg/mL**Apr 17, 2026  
45 days to decisionK260696 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k260696/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Mar 3, 2026
Decision date	Apr 17, 2026
Days to decision	45 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Liofilchem S. R. L.</b>
Location	Abruzzi, IT
Contact	Fabio Brocco
510(k) history	35 submissions · 35 cleared · 2016-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Laboratory Specialists, Inc.</b>
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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