

**K260447 ETEST Gepotidacin (GEP) (0.016-256 µg/mL)**Apr 21, 2026  
69 days to decisionK260447 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k260447/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Feb 11, 2026
Decision date	Apr 21, 2026
Days to decision	69 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>Biomérieux SA</b>
Location	Marcy-L'Étoile, FR
Contact	Stéphanie Millon-Serme
510(k) history	3 submissions · 3 cleared · 2020-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Biomérieux</b>
Contact	Stéphanie Millon-Serme

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260447/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026