

**K180936 ETEST Telavancin (TLA) (0.002-32 ug/mL)**Jul 3, 2018  
84 days to decisionK180936 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k180936/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Apr 10, 2018
Decision date	Jul 3, 2018
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomerieux S.A.</b>
Location	Craponne, FR
Contact	Asa Karlsson
510(k) history	16 submissions · 16 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180936/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026