

**K102535 ETEST TELAVANCIN IN 0.002-32 UG/ML AND  
0.016-256 UG/ML**May 16, 2011  
255 days to decisionK102535 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k102535/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Sep 3, 2010
Decision date	May 16, 2011
Days to decision	255 days
Third-party review	No
Summary / Statement	Statement

**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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