

K183031 ETEST Meropenem/Vaborbactam (MEV) (0.004/8-64/8 µg/mL)Jan 11, 2019
71 days to decisionK183031 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k183031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Nov 1, 2018
Decision date	Jan 11, 2019
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux S.A.
Location	Craponne, FR
Contact	Marine Taravant
510(k) history	16 submissions · 16 cleared · 2011-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183031/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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