CLEARED

K183360 VITEK 2 AST-Gram Negative Meropenem/Vaborbactam (<=0.5/8 – >=64/8 µg/mL)

Feb 26, 2019
84 days to decision

K183360 · Product code: **LON** · Microbiology
Source: https://www.510kdatabase.net/k183360/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Dec 4, 2018
Decision date	Feb 26, 2019
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**bioMerieux, Inc.**
Location	Mchenry, IL, US
Contact	Esther Hernandez
510(k) history	251 submissions · 250 cleared · 1983-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k183360/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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