

K183415 VITEK 2 AST-Gram Negative Imipenem (</=0.25->= 16 ug/mL)

Feb 20, 2019
72 days to decision

K183415 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k183415/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Dec 10, 2018
Decision date	Feb 20, 2019
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183415/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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