FDA 510(k) Premarket Notification

CLEARED

K193572 VITEK 2 AST-Gram Negative Imipenem/Relebactam (<=0.25/4 - >=16/4 µg/mL)

Mar 13, 2020
81 days to decision

K193572 · Product code: **LON** · Microbiology
Source: https://www.510kdatabase.net/k193572/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Dec 23, 2019
Decision date	Mar 13, 2020
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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