

K191953 ETEST Imipenem/Relebactam (IPR) (0.002/4-32/4 ug/mL)Aug 22, 2019
31 days to decisionK191953 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k191953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Jul 22, 2019
Decision date	Aug 22, 2019
Days to decision	31 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/k191953/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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