

K192050 ETEST Eravacycline (ERV) (0.002 – 32 µg/mL)Sep 27, 2019
58 days to decisionK192050 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k192050/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Jul 31, 2019
Decision date	Sep 27, 2019
Days to decision	58 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

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