

K200512 ETEST Plazomicin (PLZ) (0.016-256 µg/mL)May 7, 2020
66 days to decisionK200512 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k200512/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Mar 2, 2020
Decision date	May 7, 2020
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomérieux SA
Location	Marcy-l'Étoile, FR
Contact	Alexia Bosquet
510(k) history	3 submissions · 3 cleared · 2020-2026

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