

**K192738 ETEST Delafloxacin (DFX) (0.002-32 µg/mL)**Nov 26, 2019  
60 days to decisionK192738 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k192738/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Sep 27, 2019
Decision date	Nov 26, 2019
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomerieux S.A.</b>
Location	Craponne, FR
Contact	Sophie Quiblier
510(k) history	16 submissions · 16 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192738/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026