

**K102668 ETEST TOBRAMYCIN 0.016-256 UG/ML AND  
0.064-1024 UG/ML**Nov 17, 2010  
62 days to decisionK102668 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k102668/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Sep 16, 2010
Decision date	Nov 17, 2010
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>BIOMERIEUX</b>
Location	Craponne, FR
Contact	ASA KARLSSON
510(k) history	3 submissions · 3 cleared · 2010-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102668/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026