

**K042963 VITEK GRAM POSITIVE SUSCEPTIBILITY (GPS) CARD  
FOR ERTAPENEM**Dec 13, 2004  
47 days to decisionK042963 · Product code: **LON** · Microbiology  
Source: <https://www.510kdatabase.net/k042963/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Oct 27, 2004
Decision date	Dec 13, 2004
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>bioMerieux, Inc.</b>
Location	Mchenry, IL, US
Contact	JOLYN TENLLADO
510(k) history	251 submissions · 250 cleared · 1983-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042963/> 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 June 28, 2026