

**K152346 MicroScan Dried Gram Positive MIC/Combo Panels -
Vancomycin (0.25-64 ug/mL)**Sep 16, 2015
27 days to decisionK152346 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k152346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Aug 20, 2015
Decision date	Sep 16, 2015
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	SHANNON POPSON
Website	https://www.beckmancoulter.com
510(k) history	270 submissions · 270 cleared · 1993-2026

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...

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