

K250036 MicroScan Dried Gram-Positive MIC/Combo Panels with Daptomycin (DAP) (0.06-32 µg/mL)Aug 15, 2025
219 days to decisionK250036 · Product code: LTT · Microbiology
Source: <https://www.510kdatabase.net/k250036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Panels, Test, Susceptibility, Antimicrobial (LTT)
Date received	Jan 8, 2025
Decision date	Aug 15, 2025
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Beckman Coulter, Inc.
Location	Chaska, MN, US
Contact	Elisabeth Warriner
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,...