FDA 510(k) Premarket Notification

CLEARED

K260160 VITEK REVEAL GN AST Assay and VITEK REVEAL AST System

Jul 8, 2026
169 days to decision

K260160 · Product code: **SAN** · Microbiology
Source: https://www.510kdatabase.net/k260160/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Antimicrobial Susceptibility Test System For Positive Blood Culture Samples (SAN)
Date received	Jan 20, 2026
Decision date	Jul 8, 2026
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	**bioMerieux, Inc.**
Location	Mchenry, IL, US
Contact	Joshua Lay
510(k) history	252 submissions · 251 cleared · 1983-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k260160/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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