

K260281 VITEK 2 AST-Streptococcus Cefuroxime (≤ 0.125 - ≥ 8 $\mu\text{g/mL}$)Mar 26, 2026
56 days to decisionK260281 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k260281/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Jan 29, 2026
Decision date	Mar 26, 2026
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	BIOMERIEUX
Location	Craponne, FR
Contact	Neal Bertels
510(k) history	3 submissions · 3 cleared · 2010-2026

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