

K253573 ASTar BC G- Kit

Apr 15, 2026
149 days to decision

K253573 · Product code: **SAN** · Microbiology
Source: <https://www.510kdatabase.net/k253573/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Antimicrobial Susceptibility Test System For Positive Blood Culture Samples (SAN)
Date received	Nov 17, 2025
Decision date	Apr 15, 2026
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

Company	Q-Linea AB
Location	Uppsala, SE
Contact	Camilla Russell
510(k) history	2 submissions · 2 cleared · 2024-2026
