

K221688 ASTar BC G- Kit and ASTar InstrumentApr 26, 2024
686 days to decisionK221688 · Product code: **SAN** · Microbiology
Source: <https://www.510kdatabase.net/k221688/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Antimicrobial Susceptibility Test System For Positive Blood Culture Samples (SAN)
Date received	Jun 10, 2022
Decision date	Apr 26, 2024
Days to decision	686 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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