

**K243625 Xpert MRSA/SA SSTI**Dec 18, 2024  
23 days to decisionK243625 · Product code: **NQX** · Microbiology  
Source: <https://www.510kdatabase.net/k243625/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nucleic Acid Amplification Test, Dna, Methicillin Resistant Staphylococcus Aureus, Direct Specimen (NQX)
Date received	Nov 25, 2024
Decision date	Dec 18, 2024
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cepheid</b>
Location	Sunnyvale, CA, US
Contact	Suzette Chance
Website	<a href="https://www.cepheid.com">https://www.cepheid.com</a>
510(k) history	60 submissions · 57 cleared · 2006-2026

Cepheid is a molecular diagnostics company based in Sunnyvale, US. The company enables access to molecular diagnostic testing globally through its Xpert platform and related solutions. Cepheid has received FDA 510(k) clearances from total submissions since its first clearance in 2006. The company specializes in Microbiology devices, which represent 93% of its regulatory submissions. Its latest FDA 510(k) clearance in 2026 demonstrates continued active development and market presence. Recent cleared devices span respiratory diagnostics, infectious disease detection, antimi...