FDA 510(k) Premarket Notification

CLEARED

K101879 XPERT MRSA/SA BC (BLOOD CULTURE) ASSAY MODEL GXMRSA/SA-BC-10

Jul 28, 2010
22 days to decision

K101879 · Product code: **NQX** · Microbiology
Source: https://www.510kdatabase.net/k101879/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Nucleic Acid Amplification Test, Dna, Methicillin Resistant Staphylococcus Aureus, Direct Specimen (NQX)
Date received	Jul 6, 2010
Decision date	Jul 28, 2010
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cepheid**
Location	Sunnyvale, CA, US
Contact	RUSSEL K ENNS, PH.D.
Website	https://www.cepheid.com
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...