FDA 510(k) Premarket Notification

CLEARED

K130894 XPERT MRSA/SA BLOOD CULTURE ASSAY

Jun 20, 2013
80 days to decision

K130894 · Product code: **NQX** · Microbiology
Source: https://www.510kdatabase.net/k130894/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nucleic Acid Amplification Test, Dna, Methicillin Resistant Staphylococcus Aureus, Direct Specimen (NQX)
Date received	Apr 1, 2013
Decision date	Jun 20, 2013
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary
Other names	GENEXPERT DX SYSTEMS (GX-I, GX-II, GX-IV, GX-XVI); GENEXPERT INFINITY-48 SYSTEM; GENE

APPLICANT

Company	**Cepheid**
Location	Sunnyvale, CA, US
Contact	RAINER ZIERMANN 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k130894/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 8, 2026