

**K121539 XPERT GBS LB GENEXPERT DX SYSTEMS (GX-I, GX-IV) GENEXPERT DX SYSTEMS (GX-XVI) GENEXPERT INFINITY-48 SYSTEM (900-XXXX)**Nov 2, 2012  
162 days to decisionK121539 · Product code: NJR · Microbiology  
Source: <https://www.510kdatabase.net/k121539/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Amplification Assay System, Group B Streptococcus, Direct Specimen Test (NJR)
Date received	May 24, 2012
Decision date	Nov 2, 2012
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cepheid</b>
Location	Sunnyvale, CA, US
Contact	KERRY J FLOM
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...