

K222638 Xpert® Xpress GBS, GeneXpert® Dx System, GeneXpert® Infinity Systems

Sep 27, 2023
391 days to decision

K222638 · Product code: NJR · Microbiology
Source: <https://www.510kdatabase.net/k222638/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Amplification Assay System, Group B Streptococcus, Direct Specimen Test (NJR)
Date received	Sep 1, 2022
Decision date	Sep 27, 2023
Days to decision	391 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cepheid
Location	Sunnyvale, CA, US
Contact	Suzette Chance
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...