

K173398 Xpert Xpress Strep AApr 26, 2018
177 days to decisionK173398 · Product code: **PGX** · Microbiology
Source: <https://www.510kdatabase.net/k173398/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Groups A, C And G Beta-hemolytic Streptococcus Nucleic Acid Amplification System (PGX)
Date received	Oct 31, 2017
Decision date	Apr 26, 2018
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cepheid
Location	Sunnyvale, CA, US
Contact	Yi-Ping Lin
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...
