FDA 510(k) Premarket Notification

K250218 Xpert® FII & FV

CLEARED

Feb 21, 2025
28 days to decision

K250218 · Product code: **NPR** · Hematology
Source: https://www.510kdatabase.net/k250218/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Test, Factor Ii G20210a Mutations, Genomic Dna Pcr (NPR)
Date received	Jan 24, 2025
Decision date	Feb 21, 2025
Days to decision	28 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...