FDA 510(k) Premarket Notification

CLEARED

K180218 Xpert Xpress Flu/RSV, Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, GeneXpert Xpress II, GeneXpert Xpress IV

Jul 24, 2018
180 days to decision

K180218 · Product code: **OCC** · Microbiology
Source: https://www.510kdatabase.net/k180218/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Jan 25, 2018
Decision date	Jul 24, 2018
Days to decision	180 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...