

K162331 Xpert Xpress Flu/RSV, Xpert Nasopharyngeal Sample Collection Kit, GeneXpert Dx Systems (GX-I, GX-II, GX-IV, GX-XVI), GeneXpert Infinity-48 System and GeneXpert Infinity-48s System, GeneXpert Infinity-80 SystemFeb 9, 2017
174 days to decisionK162331 · Product code: OCC · Microbiology
Source: <https://www.510kdatabase.net/k162331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	Aug 19, 2016
Decision date	Feb 9, 2017
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cepheid
Location	Sunnyvale, CA, US
Contact	SCOTT A. CAMPBELL
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...

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