

K181289 Xpert Xpress Flu, Xpert Nasopharyngeal Sample Collection Kit, Xpert Nasal Sample Collection Kit, GeneXpert Dx Systems (GX-I, GX-II, GX-IV, GX-XVI), GeneXpert Infinity-48S System and GeneXpert Infinity-80 System

Aug 15, 2018
91 days to decision

K181289 · Product code: OCC · Microbiology
Source: <https://www.510kdatabase.net/k181289/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respiratory Virus Panel Nucleic Acid Assay System (OCC)
Date received	May 16, 2018
Decision date	Aug 15, 2018
Days to decision	91 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k181289/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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