FDA 510(k) Premarket Notification

**CLEARED**

# K151226 Xpert Flu+RSV Xpress, Xpert Nasopharyngeal Sample Collection Kit, GeneXpert Xpress System (GX-I)

Dec 3, 2015
210 days to decision

K151226 · Product code: **OCC** · Microbiology
Source: https://www.510kdatabase.net/k151226/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Dual Track |
| Device classification | Respiratory Virus Panel Nucleic Acid Assay System (OCC) |
| Date received | May 7, 2015 |
| Decision date | Dec 3, 2015 |
| Days to decision | 210 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Cepheid** |
| Location | Sunnyvale, CA, US |
| Contact | Kerry J Flom |
| 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...