CLEARED

May 23, 2019
87 days to decision

K190441 Xpert CT/NG, GeneXpert Dx System, GeneXpert Infinity-48s and GeneXpert Infinity-80 Systems, GeneXpert Infinity-48 System, Xpert Vaginal/Endocervical Specimen Collection, Xpert Urine Specimen Collection Kit, Xpert Swab Specimen Collection Kit

K190441 · Product code: **QEP** · Microbiology
Source: https://www.510kdatabase.net/k190441/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nucleic Acid Detection System For Non-viral Microorganism(s) Causing Sexually Transmitted Infections (QEP)
Date received	Feb 25, 2019
Decision date	May 23, 2019
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	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...