CLEARED

K161619 Xpert TV, Xpert Urine Specimen Collection Kit, GeneXpert Dx Systems (GX-I, GX-II, GX-IV, GX-XVI), GeneXpert Infinity-48, Genxpert Infinity-48s and GeneXpert Infinity-80 Systems

Aug 29, 2016
77 days to decision

K161619 · Product code: **OUY** · Microbiology
Source: https://www.510kdatabase.net/k161619/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trichomonas Vaginalis Nucleic Acid Amplification Test System (OUY)
Date received	Jun 13, 2016
Decision date	Aug 29, 2016
Days to decision	77 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...