

**K151565 Xpert® TV Assay on the Cepheid GeneXpert Instrument Systems (GeneXpert Dx, GeneXpert Infinity-48, GeneXpert Infinity-48s, and GeneXpertInfinity-80 systems), Xpert Vaginal/Endocervical Specimen Collection Kit, and Xpert Urine Specimen Collection Kit**Oct 16, 2015  
128 days to decisionK151565 · Product code: **OUY** · Microbiology  
Source: <https://www.510kdatabase.net/k151565/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trichomonas Vaginalis Nucleic Acid Amplification Test System (OUY)
Date received	Jun 10, 2015
Decision date	Oct 16, 2015
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cepheid</b>
Location	Sunnyvale, CA, US
Contact	KERRY J. FLOM
Website	<a href="https://www.cepheid.com">https://www.cepheid.com</a>
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, antiimi...

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151565/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 3, 2026