

**K231381 Xpert Xpress MVP**Oct 19, 2023  
160 days to decisionK231381 · Product code: **PQA** · Microbiology  
Source: <https://www.510kdatabase.net/k231381/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Vaginitis And Bacterial Vaginosis Nucleic Acid Detection System (PQA)
Date received	May 12, 2023
Decision date	Oct 19, 2023
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	GeneXpert Xpress System

**APPLICANT**

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Company	<b>Cepheid</b>
Location	Sunnyvale, CA, US
Contact	Suzette Chance
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, antimi...

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