

**K103766 XPERT FLU, GENEXPERT DX SYSTEMS, GENEXPERT INFINITY SYSTEM, GENEXPERT SYSTEM SOFTWARE VERSIONS 2.1 AND 4.0**Apr 21, 2011  
119 days to decisionK103766 · Product code: **OQW** · Microbiology  
Source: <https://www.510kdatabase.net/k103766/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	2009 H1n1 Influenza Virus (swine Origin), Nucleic Acid Or Antigen, Detection And Identification (OQW)
Date received	Dec 23, 2010
Decision date	Apr 21, 2011
Days to decision	119 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...