

**K082118 XPERT HEMOSIL FACTOR II & FACTOR V ASSAY**Sep 18, 2009  
417 days to decisionK082118 · Product code: **NPQ** · Pathology  
Source: <https://www.510kdatabase.net/k082118/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Factor V Leiden Mutations, Genomic Dna Pcr (NPQ)
Date received	Jul 28, 2008
Decision date	Sep 18, 2009
Days to decision	417 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cepheid</b>
Location	Sunnyvale, CA, US
Contact	RUSSEL K ENNS
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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