

K091109 XPERT C. DIFFICILEJul 9, 2009
84 days to decisionK091109 · Product code: **LLH** · Microbiology
Source: <https://www.510kdatabase.net/k091109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Apr 16, 2009
Decision date	Jul 9, 2009
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cepheid
Location	Sunnyvale, CA, US
Contact	RUSSEL K ENNS
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...
