FDA 510(k) Premarket Notification

K160901 Xpert Carba-R

CLEARED

Jun 29, 2016
89 days to decision

K160901 · Product code: **POC** · Microbiology
Source: https://www.510kdatabase.net/k160901/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nucleic Acid Amplification Test, Dna, Antimicrobial Resistance Marker, Direct Specimen (POC)
Date received	Apr 1, 2016
Decision date	Jun 29, 2016
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cepheid**
Location	Sunnyvale, CA, US
Contact	SCOTT A. CAMPBELL
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...