

K143302 Xpert MTB/RIF Assay, GeneXpert Dx, GeneXpert Infinity-48, GeneXpert Infinity-48s, GeneXpert Infinity-80Feb 12, 2015
87 days to decisionK143302 · Product code: **PEU** · Microbiology
Source: <https://www.510kdatabase.net/k143302/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nucleic Acid-based, Mycobacterium Tuberculosis Complex, Resistance Marker, Direct Specimen (PEU)
Date received	Nov 17, 2014
Decision date	Feb 12, 2015
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cepheid
Location	Sunnyvale, CA, US
Contact	KERRY J FLOM
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...

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Device record: <https://www.510kdatabase.net/k143302/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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