CLEARED

K160829 illumigene Mycoplasma Direct DNA Amplification Assay, illumigene Mycoplasma Direct External Controls, illumipro-10

Jun 13, 2016
80 days to decision

K160829 · Product code: **OZX** · Microbiology
Source: https://www.510kdatabase.net/k160829/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mycoplasma Pneumoniae Dna Assay System (OZX)
Date received	Mar 25, 2016
Decision date	Jun 13, 2016
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Meridian Bioscience, Inc.**
Location	Cincinnati, OH, US
Contact	MICHELLE L. SMITH
Website	https://www.meridianbioscience.com
510(k) history	38 submissions · 37 cleared · 2003-2025

Meridian Bioscience, Inc. is a diagnostic and life science solutions company with a manufacturing facility in Cincinnati, US. The company develops integrated diagnostic products and molecular reagents for clinical and research applications. Meridian has received FDA 510(k) clearances from total submissions since 2003. The company specializes exclusively in Microbiology devices, including molecular detection assays, pathogen identification systems, and diagnostic analyzers. The latest clearance in 2025 reflects continued regulatory activity and product innovation. Recent c...