FDA 510(k) Premarket Notification

CLEARED

K152800 illumigene Mycoplasma DNA Amplification Assay

Oct 23, 2015
25 days to decision

K152800 · Product code: **OZX** · Microbiology
Source: https://www.510kdatabase.net/k152800/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mycoplasma Pneumoniae Dna Assay System (OZX)
Date received	Sep 28, 2015
Decision date	Oct 23, 2015
Days to decision	25 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Meridian Bioscience, Inc.**
Location	Cincinnati, OH, US
Contact	Stefanie Johns
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...