FDA 510(k) Premarket Notification

CLEARED

K152285 illumigene Pertussis DNA Amplification Assay

Nov 10, 2015
90 days to decision

K152285 · Product code: **OZZ** · Microbiology
Source: https://www.510kdatabase.net/k152285/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bordetella Pertussis Dna Assay System (OZZ)
Date received	Aug 12, 2015
Decision date	Nov 10, 2015
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Meridian Bioscience, Inc.**
Location	Cincinnati, OH, US
Contact	SUSAN ROLIH
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...