FDA 510(k) Premarket Notification

K163273 TRU Legionella

CLEARED

Feb 21, 2017
92 days to decision

K163273 · Product code: **MJH** · Microbiology
Source: https://www.510kdatabase.net/k163273/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Legionella, Spp., Elisa (MJH)
Date received	Nov 21, 2016
Decision date	Feb 21, 2017
Days to decision	92 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Meridian Bioscience, Inc.**
Location	Cincinnati, OH, US
Contact	Lauren Davis
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...