FDA 510(k) Premarket Notification

K182559 PREMIER Platinum HpSA PLUS

CLEARED

Nov 5, 2018
49 days to decision

K182559 · Product code: **LYR** · Microbiology
Source: https://www.510kdatabase.net/k182559/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Sep 17, 2018
Decision date	Nov 5, 2018
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Meridian Bioscience, Inc.**
Location	Cincinnati, OH, US
Contact	Jack Rogers
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...