FDA 510(k) Premarket Notification

K192817 Curian HpSA, Curian Analyzer

CLEARED

Mar 13, 2020
164 days to decision

K192817 · Product code: **LYR** · Microbiology
Source: https://www.510kdatabase.net/k192817/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Oct 1, 2019
Decision date	Mar 13, 2020
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Meridian Bioscience, Inc.**
Location	Cincinnati, OH, US
Contact	Cathlena Martinez
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...