

K230901 Premier HpSA Flex (619096)Jul 3, 2023
94 days to decisionK230901 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k230901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Helicobacter Pylori (LYR)
Date received	Mar 31, 2023
Decision date	Jul 3, 2023
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Meridian Bioscience, Inc.
Location	Cincinnati, OH, US
Contact	Heather Planck
510(k) history	38 submissions · 37 cleared · 2003-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230901/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026