

K032222 IMMUNOCARDSTAT HPSADec 5, 2003
137 days to decisionK032222 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k032222/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Helicobacter Pylori (LYR) |
| Date received | Jul 21, 2003 |
| Decision date | Dec 5, 2003 |
| Days to decision | 137 days |
| Third-party review | No |
| Summary / Statement | Summary |

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...
