

**K912215 PYLORITRAK**Oct 4, 1991  
137 days to decisionK912215 · Product code: LZR · Microbiology  
Source: <https://www.510kdatabase.net/k912215/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Helicobacter Pylori (LYR)          |
| Date received         | May 20, 1991                       |
| Decision date         | Oct 4, 1991                        |
| Days to decision      | 137 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Bainbridge Laboratories, Inc.</b>  |
| Location       | Bainbridge Island, WA, US             |
| Contact        | MAX LYON                              |
| 510(k) history | 2 submissions · 2 cleared · 1988-1991 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912215/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026