

K904738 PYLORI STAT TEST KITMay 7, 1991
201 days to decisionK904738 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k904738/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Helicobacter Pylori (LYR) |
| Date received | Oct 18, 1990 |
| Decision date | May 7, 1991 |
| Days to decision | 201 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Whittaker Bioproducts, Inc. |
| Location | Walkersville, MD, US |
| Contact | LEIF E OLSEN |
| 510(k) history | 30 submissions · 30 cleared · 1984-1992 |

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