

K973508 PYLORI DETECT IGGMar 10, 1998
175 days to decisionK973508 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k973508/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Helicobacter Pylori (LYR) |
| Date received | Sep 16, 1997 |
| Decision date | Mar 10, 1998 |
| Days to decision | 175 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Micro Detect, Inc. |
| Location | Tustin, CA, US |
| Contact | MEHDI ALEM PH.D. |
| 510(k) history | 11 submissions · 11 cleared · 1998-2001 |

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