

**K000463 IMMULITE H. PYLORI IGG AND IMMULITE 2000 H.
PYLORI IGG**Jun 1, 2000
111 days to decisionK000463 · Product code: LYR · Microbiology
Source: <https://www.510kdatabase.net/k000463/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Helicobacter Pylori (LYR) |
| Date received | Feb 11, 2000 |
| Decision date | Jun 1, 2000 |
| Days to decision | 111 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Diagnostic Products Corp. |
| Location | Mchenry, IL, US |
| Contact | EDWARD M LEVINE |
| 510(k) history | 321 submissions · 321 cleared · 1976-2006 |

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