

**K081064 GIARDIA FECAL ANTIGEN DETECTION LATERAL
FLOW KIT, MODEL GL-LF**Jan 14, 2009
275 days to decisionK081064 · Product code: **MHI** · Microbiology
Source: <https://www.510kdatabase.net/k081064/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Giardia Spp. (MHI) |
| Date received | Apr 14, 2008 |
| Decision date | Jan 14, 2009 |
| Days to decision | 275 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ivd Research, Inc. |
| Location | Carlsbad, CA, US |
| Contact | MICHAEL WIENHOLT |
| 510(k) history | 5 submissions · 5 cleared · 2002-2009 |

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