

K942098 PROSPECT GIARDIASep 9, 1994
148 days to decisionK942098 · Product code: **MHI** · Microbiology
Source: <https://www.510kdatabase.net/k942098/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Giardia Spp. (MHI) |
| Date received | Apr 14, 1994 |
| Decision date | Sep 9, 1994 |
| Days to decision | 148 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Alexon, Inc. |
| Location | Mountain View, CA, US |
| Contact | SUSAN TURNER |
| 510(k) history | 10 submissions · 10 cleared · 1991-1994 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942098/> Data sourced from FDA 510(k) public records (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. - Generated June 30, 2026