

**K982245 TRIAGE, PARASITE PANEL, TRIAGE
CRYPTOSPORIDIUM AND ENTAMOEBIA HISTOLYTICA, TRIAGE
CRYPTOSPORIDIUM AND GIARDIA LAMBLIA**

Oct 6, 1998
102 days to decision

K982245 · Product code: **MHI** · Microbiology
Source: <https://www.510kdatabase.net/k982245/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Giardia Spp. (MHI)
Date received	Jun 26, 1998
Decision date	Oct 6, 1998
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosite Incorporated
Location	San Diego, CA, US
Contact	JOHN F BRUNI
510(k) history	46 submissions · 45 cleared · 1990-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k982245/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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