

K120001 UNIGOLD GIARDIAMar 1, 2013
423 days to decisionK120001 · Product code: **MHI** · Microbiology
Source: <https://www.510kdatabase.net/k120001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Giardia Spp. (MHI)
Date received	Jan 3, 2012
Decision date	Mar 1, 2013
Days to decision	423 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trinity Biotech
Location	Jamestown, NY, US
Contact	LUPE KAGAN
510(k) history	5 submissions · 5 cleared · 2009-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k120001/> 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 May 31, 2026