

**K121565 UNI-GOLD CRYPTOSPORIDIUM**Feb 8, 2013  
255 days to decisionK121565 · Product code: **MHJ** · Microbiology  
Source: <https://www.510kdatabase.net/k121565/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cryptosporidium Spp. (MHJ)
Date received	May 29, 2012
Decision date	Feb 8, 2013
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121565/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 31, 2026