

**K031965 XPECT CRYPTOSPORIDIUM LATERAL FLOW ASSAY,
MODEL 2451020**Nov 14, 2003
141 days to decisionK031965 · Product code: **MHJ** · Microbiology
Source: <https://www.510kdatabase.net/k031965/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cryptosporidium Spp. (MHJ)
Date received	Jun 26, 2003
Decision date	Nov 14, 2003
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Remel, Inc.
Location	Lenexa, KS, US
Contact	RICHARD TYSON
510(k) history	17 submissions · 17 cleared · 1994-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k031965/> 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 1, 2026