

K121411 SHIGA TOXIN CHEKOct 2, 2012
144 days to decisionK121411 · Product code: **GMZ** · Microbiology
Source: <https://www.510kdatabase.net/k121411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Types, Escherichia Coli (GMZ)
Date received	May 11, 2012
Decision date	Oct 2, 2012
Days to decision	144 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Techlab Inc., Corporate Research Center
Location	Blacksburg, VA, US
Contact	DONNA T LINK
510(k) history	5 submissions · 5 cleared · 2007-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121411/> 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 13, 2026