

K942705 E. COLI 0157 ELISA STOOL ASSAYSep 27, 1995
476 days to decisionK942705 · Product code: **GMZ** · Microbiology
Source: <https://www.510kdatabase.net/k942705/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, All Types, Escherichia Coli (GMZ)
Date received	Jun 8, 1994
Decision date	Sep 27, 1995
Days to decision	476 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lmd Laboratories
Location	San Diego, CA, US
Contact	DAVE LAMBILLOTTE
510(k) history	12 submissions · 12 cleared · 1984-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942705/> 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 29, 2026