

K944421 E.COLI 0157 LATEX TESTDec 15, 1994
119 days to decisionK944421 · Product code: **GMZ** · Microbiology
Source: <https://www.510kdatabase.net/k944421/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigens, All Types, Escherichia Coli (GMZ) |
| Date received | Aug 18, 1994 |
| Decision date | Dec 15, 1994 |
| Days to decision | 119 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Pro-Lab Diagnostics |
| Location | Ontario, CA |
| Contact | LYNN RAE |
| 510(k) history | 5 submissions · 5 cleared · 1992-1994 |

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