

K971663 WELLCOLEX E.COLI O157:H7Dec 30, 1997
238 days to decisionK971663 · Product code: **GMZ** · Microbiology
Source: <https://www.510kdatabase.net/k971663/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antigens, All Types, Escherichia Coli (GMZ) |
| Date received | May 6, 1997 |
| Decision date | Dec 30, 1997 |
| Days to decision | 238 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Murex Biotech , Ltd. |
| Location | Dartford,Kent, GB |
| Contact | REBECCA VINE |
| 510(k) history | 1 submissions · 1 cleared · 1997-1997 |

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