

K983842 BIOTEST ANTI-EBV RECOMBINANT, EA IGMJun 9, 1999
222 days to decisionK983842 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k983842/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Epstein-barr Virus, Other (LSE) |
| Date received | Oct 30, 1998 |
| Decision date | Jun 9, 1999 |
| Days to decision | 222 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biotest Diagnostics Corp. |
| Location | Denville, NJ, US |
| Contact | PATRICIA E BONNESS |
| 510(k) history | 5 submissions · 5 cleared · 1996-1999 |

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