

K936252 COXSACKIEVIRUS B@ MONOCLONAL ANTIBODYSep 8, 1995
617 days to decisionK936252 · Product code: **GNM** · Microbiology
Source: <https://www.510kdatabase.net/k936252/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antisera, Fluorescent, Coxsackievirus A 1-24, B 1-6 (GNM) |
| Date received | Dec 30, 1993 |
| Decision date | Sep 8, 1995 |
| Days to decision | 617 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Light Diagnostics |
| Location | Temecula, CA, US |
| Contact | PRISCILLA ZIA, PH.D. |
| 510(k) history | 19 submissions · 19 cleared · 1993-1999 |

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