

K936251 COXSACKIEVIRUS B3 MONOCLONAL ANTIBODYSep 8, 1995
617 days to decisionK936251 · Product code: **GNM** · Microbiology
Source: <https://www.510kdatabase.net/k936251/>**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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k936251/> 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