

K936253 COXSACKIEVIRUS B4 MONOCLONAL ANTIBODY

Sep 8, 1995
617 days to decision

K936253 · Product code: **GNM** · Microbiology
Source: <https://www.510kdatabase.net/k936253/>

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	RICHARD P TRIGLIA
510(k) history	19 submissions · 19 cleared · 1993-1999

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Device record: <https://www.510kdatabase.net/k936253/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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