

K936145 COXSACKIEVIRUS B1 MONOCLONAL ANTIBODYSep 8, 1995
620 days to decisionK936145 · Product code: **GNM** · Microbiology
Source: <https://www.510kdatabase.net/k936145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Fluorescent, Coxsackievirus A 1-24, B 1-6 (GNM)
Date received	Dec 27, 1993
Decision date	Sep 8, 1995
Days to decision	620 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chemicon Intl., Inc.
Location	Temecula, CA, US
Contact	PRICILLA ZIA
510(k) history	8 submissions · 8 cleared · 1995-1999

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