

K942171 CMV EARLY ANTIGEN TESTJun 30, 1994
56 days to decisionK942171 · Product code: **GQI** · Microbiology
Source: <https://www.510kdatabase.net/k942171/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Cf, Cytomegalovirus (GQI)
Date received	May 5, 1994
Decision date	Jun 30, 1994
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Neogenex
Location	Everett, WA, US
Contact	D.F. ROBERTS
510(k) history	20 submissions · 20 cleared · 1994-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k942171/> 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 May 14, 2026