

K951800 CMV IGG HUMAN SERUM CONTROLSNov 16, 1995
212 days to decisionK951800 · Product code: **GQI** · Microbiology
Source: <https://www.510kdatabase.net/k951800/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Cf, Cytomegalovirus (GQI)
Date received	Apr 18, 1995
Decision date	Nov 16, 1995
Days to decision	212 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pyramid Biological Corp.
Location	Van Nuys, CA, US
Contact	JEANETTE R PORRETTA
510(k) history	12 submissions · 12 cleared · 1993-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951800/> 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