

K802930 CYTOMEGALO VIRUS & CONTROLSJan 9, 1981
51 days to decisionK802930 · Product code: **GQH** · Microbiology
Source: <https://www.510kdatabase.net/k802930/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Cytomegalovirus (GQH)
Date received	Nov 19, 1980
Decision date	Jan 9, 1981
Days to decision	51 days
Third-party review	No

APPLICANT

Company	Orion Diagnostica, Inc.
Location	Mchenry, IL, US
510(k) history	28 submissions · 28 cleared · 1980-1994

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k802930/> 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 30, 2026