

K863488 ENZYGNOST ANTI-CMV IGG TESTJul 20, 1987
314 days to decisionK863488 · Product code: **GQI** · Microbiology
Source: <https://www.510kdatabase.net/k863488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Cf, Cytomegalovirus (GQI)
Date received	Sep 9, 1986
Decision date	Jul 20, 1987
Days to decision	314 days
Third-party review	No

APPLICANT

Company	Behring Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	JOHN E HUGHES
510(k) history	145 submissions · 145 cleared · 1976-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k863488/>; 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 28, 2026