

K842529 AMIZYME-CMV KITDec 6, 1985
526 days to decisionK842529 · Product code: **GQI** · Immunology
Source: <https://www.510kdatabase.net/k842529/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Cf, Cytomegalovirus (GQI)
Date received	Jun 28, 1984
Decision date	Dec 6, 1985
Days to decision	526 days
Third-party review	No

APPLICANT

Company	Amico Lab, Inc.
Location	Mchenry, IL, US
510(k) history	32 submissions · 32 cleared · 1982-1985

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Device record: <https://www.510kdatabase.net/k842529/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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