

**K843189 CYTOMEGALOVIRUS IGG EIA TEST KIT**Jan 8, 1986  
513 days to decisionK843189 · Product code: **GQI** · Immunology  
Source: <https://www.510kdatabase.net/k843189/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antiserum, Cf, Cytomegalovirus (GQI)
Date received	Aug 13, 1984
Decision date	Jan 8, 1986
Days to decision	513 days
Third-party review	No

**APPLICANT**

---

Company	<b>Labsystems, Inc.</b>
Location	Walker, MI, US
510(k) history	17 submissions · 17 cleared · 1984-1993

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k843189/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026