

**K894002 CYTOMEGALOVIRUS FLUORESCENT MONOCLONAL ANTIBODY**Aug 10, 1989  
66 days to decisionK894002 · Product code: **LIN** · Microbiology  
Source: <https://www.510kdatabase.net/k894002/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, Conjugated Fluorescent, Cytomegalovirus (LIN)
Date received	Jun 5, 1989
Decision date	Aug 10, 1989
Days to decision	66 days
Third-party review	No

**APPLICANT**

---

Company	<b>Baxter Healthcare Corp</b>
Location	Mchenry, IL, US
Contact	LORRAINE WEAVER
510(k) history	505 submissions · 496 cleared · 1977-2019

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k894002/> 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 May 17, 2026