

**K872576 COLORGENE DNA HYBRIDIZATION TEST CMV  
CONFIRMATION**Dec 4, 1987  
157 days to decisionK872576 · Product code: **GQH** · Microbiology  
Source: <https://www.510kdatabase.net/k872576/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigen, Cf (including Cf Control), Cytomegalovirus (GQH)
Date received	Jun 30, 1987
Decision date	Dec 4, 1987
Days to decision	157 days
Third-party review	No

**APPLICANT**

---

Company	<b>Enzo Biochem, Inc.</b>
Location	New York, NY, US
Contact	PAULA J OLSIEWSKI
510(k) history	5 submissions · 5 cleared · 1987-1988

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k872576/>. 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 29, 2026