

**K861212 DIRECT ACU-SLIDE TEST**Jul 7, 1986  
98 days to decisionK861212 · Product code: **JHJ** · Chemistry  
Source: <https://www.510kdatabase.net/k861212/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agglutination Method, Human Chorionic Gonadotropin (JHJ)
Date received	Mar 31, 1986
Decision date	Jul 7, 1986
Days to decision	98 days
Third-party review	No

**APPLICANT**

---

Company	<b>Cal-Tech Diagnostics, Inc.</b>
Location	Monterey Park, CA, US
Contact	CHEN, PH.D.
510(k) history	3 submissions · 3 cleared · 1985-1986

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861212/>; 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