

K853247 ACU-SLIDE-TESTSep 4, 1985
34 days to decisionK853247 · Product code: **JHJ** · Toxicology
Source: <https://www.510kdatabase.net/k853247/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agglutination Method, Human Chorionic Gonadotropin (JHJ) |
| Date received | Aug 1, 1985 |
| Decision date | Sep 4, 1985 |
| Days to decision | 34 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Cal-Tech Diagnostics, Inc. |
| Location | Monterey Park, CA, US |
| Contact | SHIV-JANE CHEN |
| 510(k) history | 3 submissions · 3 cleared · 1985-1986 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853247/>; 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