

K860945 DIRECTACLONE CG SLIDE PREGNANCY TESTMay 2, 1986
51 days to decisionK860945 · Product code: **JHJ** · Chemistry
Source: <https://www.510kdatabase.net/k860945/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agglutination Method, Human Chorionic Gonadotropin (JHJ) |
| Date received | Mar 12, 1986 |
| Decision date | May 2, 1986 |
| Days to decision | 51 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Pacific Biotech, Inc. |
| Location | Mchenry, IL, US |
| Contact | SHU-CHING CHENG |
| 510(k) history | 29 submissions · 29 cleared · 1983-1993 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860945/>; 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 30, 2026