

K863199 CARDS(TM) HCG-URINESep 15, 1986
27 days to decisionK863199 · Product code: **JHI** · Chemistry
Source: <https://www.510kdatabase.net/k863199/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received | Aug 19, 1986 |
| Decision date | Sep 15, 1986 |
| Days to decision | 27 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/k863199/>; 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