

**K945514 LIFESIGN(TM) 1, BIOSIGN(TM) 1, LIFESIGN PLUS(TM),
LIFESIGN(TM) HCG**Feb 10, 1995
93 days to decisionK945514 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k945514/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Kit, Test, Pregnancy, Hcg, Over The Counter (LCX) |
| Date received | Nov 9, 1994 |
| Decision date | Feb 10, 1995 |
| Days to decision | 93 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Princeton BioMeditech Corp. |
| Location | Monmouth Junction, NJ, US |
| Contact | JEMO KANG |
| 510(k) history | 72 submissions · 72 cleared · 1994-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k945514/>; 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 May 25, 2026