

K780321 PREGNANCY TEST KIT, OVER-THE-COUNTERApr 4, 1978
39 days to decisionK780321 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k780321/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Kit, Test, Pregnancy, Hcg, Over The Counter (LCX) |
| Date received | Feb 24, 1978 |
| Decision date | Apr 4, 1978 |
| Days to decision | 39 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Intl. Diagnostic, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 6 submissions · 6 cleared · 1978-1984 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k780321/> 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 July 1, 2026