

K974059 ONE STEP MIDSTREAM HCG PREGNANCY TESTApr 9, 1998
164 days to decisionK974059 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k974059/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Kit, Test, Pregnancy, Hcg, Over The Counter (LCX) |
| Date received | Oct 27, 1997 |
| Decision date | Apr 9, 1998 |
| Days to decision | 164 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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|----------------|--|
| Company | International Newtech Development, Inc. |
| Location | Richmond, B.C., CA |
| Contact | BENNY WANG |
| 510(k) history | 8 submissions · 8 cleared · 1995-2000 |

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