

**K123050 EGENS ONE STEP HCG URINE PREGNANCY TEST
KIT(S) (STRIP, CASSETTE, MIDSTREAM I AND MIDSTREAM II)**Feb 5, 2013
130 days to decisionK123050 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k123050/>**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 | Sep 28, 2012 |
| Decision date | Feb 5, 2013 |
| Days to decision | 130 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Nantong Biotechnology Co., Ltd. |
| Location | Gaithersburg, MD, US |
| Contact | JOE XIA |
| 510(k) history | 1 submissions · 1 cleared · 2013-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123050/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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