

K192123 HIGHTOP Pregnancy Rapid Test Cassette, HIGHTOP Pregnancy Rapid Test Strip, HIGHTOP Pregnancy Rapid Test MidstreamSep 5, 2019
30 days to decisionK192123 · Product code: **LCX** · Chemistry
Source: <https://www.510kdatabase.net/k192123/>**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 | Aug 6, 2019 |
| Decision date | Sep 5, 2019 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Qingdao Hightop Biotech Co., Ltd. |
| Location | Qingdao, CN |
| Contact | Allen Lee |
| 510(k) history | 3 submissions · 3 cleared · 2019-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192123/> 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 26, 2026