

**K032159 CARESTART-PREGNANCY AND CARESTART PLUS-PREGNANCY**Sep 5, 2003  
52 days to decisionK032159 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k032159/>**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         | Jul 15, 2003                                      |
| Decision date         | Sep 5, 2003                                       |
| Days to decision      | 52 days   |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Access Bio Incorporate</b>         |
| Location       | North Brunswick, NJ, US               |
| Contact        | YOUNG HO CHOI                         |
| 510(k) history | 4 submissions · 4 cleared · 2003-2005 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032159/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026