

**K993375 CDS LTX CONTROL LATEX PARTICLE SUSPENSION  
AND PRIMER**Dec 20, 1999  
74 days to decisionK993375 · Product code: **KRX** · Hematology  
Source: <https://www.510kdatabase.net/k993375/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Abbreviated                        |
| Device classification | Calibrator For Cell Indices (KRX)  |
| Date received         | Oct 7, 1999                        |
| Decision date         | Dec 20, 1999                       |
| Days to decision      | 74 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>Clinical Diagnostic Solutions, Inc.</b> |
| Location       | Plantation, FL, US                         |
| Contact        | COLIN ALDERSLEY                            |
| 510(k) history | 3 submissions · 3 cleared · 1999-2004      |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k993375/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026