

**K061064 COULTER LIN-C LINEARITY CONTROL, MODELS  
7547065, 723503**May 17, 2006  
30 days to decisionK061064 · Product code: **JPK** · Hematology  
Source: <https://www.510kdatabase.net/k061064/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Mixture, Hematology Quality Control (JPK) |
| Date received         | Apr 17, 2006                              |
| Decision date         | May 17, 2006                              |
| Days to decision      | 30 days                                   |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Beckman Coulter, Inc.</b>  |
| Location       | Chaska, MN, US  |
| Contact        | NANCY NADLER  |
| Website        | <a href="https://www.beckmancoulter.com">https://www.beckmancoulter.com</a> |
| 510(k) history | 270 submissions · 270 cleared · 1993-2026                                   |

Beckman Coulter, Inc. is a diagnostic device manufacturer headquartered in Chaska, US. The company specializes in clinical laboratory and immunodiagnostic systems. Beckman Coulter has received FDA 510(k) clearances from total submissions since its first clearance in 1993. The company maintains active regulatory status, with the latest clearance in 2026. Its portfolio spans chemistry devices, microbiology testing systems, hematology analyzers, and immunoassay platforms. Recent cleared devices include chemistry assays for cardiac markers, microbiology susceptibility panels,...