

**K061574 COULTER LH 750 HEMATOLOGY ANALYZER, MODEL 6605632**Jul 21, 2006  
44 days to decisionK061574 · Product code: **GKZ** · Hematology  
Source: <https://www.510kdatabase.net/k061574/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Counter, Differential Cell (GKZ)   |
| Date received         | Jun 7, 2006                        |
| Decision date         | Jul 21, 2006                       |
| Days to decision      | 44 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,...