

**K080812 HEMOCCULT ICT**Jun 25, 2008  
93 days to decisionK080812 · Product code: **KHE** · Hematology  
Source: <https://www.510kdatabase.net/k080812/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Reagent, Occult Blood (KHE)        |
| Date received         | Mar 24, 2008                       |
| Decision date         | Jun 25, 2008                       |
| Days to decision      | 93 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        | SYLVIA ZORICH   |
| 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,...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k080812/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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