

**K961312 HEMOCUE B-HEMOGLOBIN SYSTEM**Sep 24, 1996  
173 days to decisionK961312 · Product code: **GKR** · Hematology  
Source: <https://www.510kdatabase.net/k961312/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | System, Hemoglobin, Automated (GKR) |
| Date received         | Apr 4, 1996                         |
| Decision date         | Sep 24, 1996                        |
| Days to decision      | 173 days                            |
| Third-party review    | No                                  |
| Summary / Statement   | Statement                           |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Hemocue, Inc.</b>                  |
| Location       | Potomac, MD, US                       |
| Contact        | ROBERT J SLOMOF                       |
| 510(k) history | 9 submissions · 9 cleared · 1991-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k961312/> 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 28, 2026