

**K041234 HEMOCUE HEMOGLOBIN 201DM ANALYZING SYSTEM**Jun 10, 2004  
31 days to decisionK041234 · Product code: **GKR** · Hematology  
Source: <https://www.510kdatabase.net/k041234/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Special                             |
| Device classification | System, Hemoglobin, Automated (GKR) |
| Date received         | May 10, 2004                        |
| Decision date         | Jun 10, 2004                        |
| Days to decision      | 31 days                             |
| Third-party review    | No                                  |
| Summary / Statement   | Statement                           |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Hemocue, Inc.</b>                  |
| Location       | Potomac, MD, US                       |
| Contact        | R.J. SLOMOFF                          |
| 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/k041234/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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