

**K760581 HA/5 HEMATOLOGY ANALYZER**Nov 9, 1976  
67 days to decisionK760581 · Product code: **GKL** · Hematology  
Source: <https://www.510kdatabase.net/k760581/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Counter, Cell, Automated (particle Counter) (GKL) |
| Date received         | Sep 3, 1976                                       |
| Decision date         | Nov 9, 1976                                       |
| Days to decision      | 67 days   |
| Third-party review    | No  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Bd Becton Dickinson Vacutainer Systems Preanalytic</b> |
| Location       | Washington, DC, US  |
| 510(k) history | 632 submissions · 625 cleared · 1976-2001                 |

---

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

Device record: <https://www.510kdatabase.net/k760581/> 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 May 21, 2026