

**K001145 SYSMEX AUTOMATED COAGULATION ANALYZER,  
MODEL CA-6000**May 11, 2000  
31 days to decisionK001145 · Product code: **GKP** · Hematology  
Source: <https://www.510kdatabase.net/k001145/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Instrument, Coagulation, Automated (GKP) |
| Date received         | Apr 10, 2000                             |
| Decision date         | May 11, 2000                             |
| Days to decision      | 31 days                                  |
| Third-party review    | No                                       |
| Combination product   | No                                       |
| PCCP authorized       | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dade Behring, Inc.</b>                 |
| Location       | Newark,, DE, US                           |
| Contact        | RADAMES RIESGO                            |
| 510(k) history | 343 submissions · 343 cleared · 1978-2010 |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001145/> 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 19, 2026