

**K865105 AFFINITY(TM) SYSTEM**Mar 12, 1987  
72 days to decisionK865105 · Product code: **JJE** · Chemistry  
Source: <https://www.510kdatabase.net/k865105/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                  |
| Submission type       | Traditional   |
| Device classification | Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE) |
| Date received         | Dec 30, 1986  |
| Decision date         | Mar 12, 1987  |
| Days to decision      | 72 days   |
| Third-party review    | No  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k865105/>; 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 22, 2026