

**K974006 BECTON DICKINSON TWINPAK**Jan 22, 1998  
93 days to decisionK974006 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k974006/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received         | Oct 21, 1997                           |
| Decision date         | Jan 22, 1998                           |
| Days to decision      | 93 days                                |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Bd Becton Dickinson Vacutainer Systems Preanalytic</b> |
| Location       | Washington, DC, US  |
| Contact        | GREG MORGON   |
| 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/k974006/> 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