

**K021005 SIMPLICITY EASY ACCESS II INFUSION SET FOR  
INFUSION AND/OR INJECTION OF FLUIDS INTO THE BODY  
BELOW THE SURFACE**Apr 25, 2002  
28 days to decisionK021005 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k021005/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Abbreviated                              |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received         | Mar 28, 2002                             |
| Decision date         | Apr 25, 2002                             |
| Days to decision      | 28 days                                  |
| Third-party review    | No                                       |
| Summary / Statement   | Statement                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Sterling Medivations, Inc.</b>       |
| Location       | Wayzata, MN, US                         |
| Contact        | JOEL DOUGLAS                            |
| 510(k) history | 27 submissions · 27 cleared · 2000-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k021005/> 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 July 2, 2026