

**K090459 DISPOSABLE TPE INFUSION SET**Oct 13, 2009  
232 days to decisionK090459 · Product code: **FPA** · General Hospital  
Source: <https://www.510kdatabase.net/k090459/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received         | Feb 23, 2009                             |
| Decision date         | Oct 13, 2009                             |
| Days to decision      | 232 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Shan Dong Wei Gao Group Medical Polymer Products</b> |
| Location       | Shan Nan Er Rd., Shanghai, CN                           |
| Contact        | Diana Hong  |
| 510(k) history | 3 submissions · 3 cleared · 2009-2009                   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090459/> 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 22, 2026