

**K970201 GSI CANNULA WITH INTRODUCER**Apr 21, 1997  
90 days to decisionK970201 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k970201/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Introducer, Catheter (DYB)         |
| Date received         | Jan 21, 1997                       |
| Decision date         | Apr 21, 1997                       |
| Days to decision      | 90 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>General Surgical Innovations</b>     |
| Location       | Portola Valley, CA, US                  |
| Contact        | CATHLEEN MANTOR                         |
| 510(k) history | 14 submissions · 13 cleared · 1993-1999 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970201/> 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 4, 2026