

**K040520 SLIP UROLOGY INTRODUCER SHEATH**May 20, 2004  
83 days to decisionK040520 · Product code: **KNY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k040520/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Accessories, Catheter, G-u (KNY)   |
| Date received         | Feb 27, 2004                       |
| Decision date         | May 20, 2004                       |
| Days to decision      | 83 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Percutaneous Systems, Inc.</b>     |
| Location       | Washington, Dc, DC, US                |
| Contact        | HOWARD M HOLSTEIN                     |
| 510(k) history | 6 submissions · 6 cleared · 2004-2011 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040520/> 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 19, 2026