

**K020379 PPD BALLOON DILATATION CATHETER**May 6, 2002  
90 days to decisionK020379 · Product code: **KNT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k020379/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Special   |
| Device classification | Tubes, Gastrointestinal (and Accessories) (KNT) |
| Date received         | Feb 5, 2002                                     |
| Decision date         | May 6, 2002                                     |
| Days to decision      | 90 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Telemed Systems, Inc.</b>            |
| Location       | Hudson, MA, US                          |
| Contact        | MICHAEL CARROLL                         |
| 510(k) history | 22 submissions · 22 cleared · 1990-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k020379/> 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 22, 2026