

**K970041 ASCEND BALLOON DAILATION CATHETER**Mar 19, 1997  
72 days to decisionK970041 · Product code: **EZN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970041/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Dilator, Catheter, Ureteral (EZN)  |
| Date received         | Jan 6, 1997                        |
| Decision date         | Mar 19, 1997                       |
| Days to decision      | 72 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Cook Urological, Inc.</b>              |
| Location       | Spencer, IN, US                           |
| Contact        | TAMMY BACON                               |
| 510(k) history | 104 submissions · 102 cleared · 1986-2011 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970041/> 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