

**K971801 LAPAROTOMY BLADDER NECK SUSPENSION KIT**Jul 22, 1997  
68 days to decisionK971801 · Product code: **EZL** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k971801/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)      |
| Submission type       | Traditional                             |
| Device classification | Catheter, Retention Type, Balloon (EZL) |
| Date received         | May 15, 1997                            |
| Decision date         | Jul 22, 1997                            |
| Days to decision      | 68 days                                 |
| Third-party review    | No                                      |
| Summary / Statement   | Summary                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Louisville Laboratories, Inc.</b>    |
| Location       | Weston, MA, US                          |
| Contact        | MARY MCNAMARA-CULLINANE                 |
| 510(k) history | 12 submissions · 12 cleared · 1989-1998 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971801/> 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 14, 2026