

K892855 URETHRAL BALLOON DILATION CATHETER SETNov 17, 1989
213 days to decisionK892855 · Product code: **KOE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k892855/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dilator, Urethral (KOE) |
| Date received | Apr 18, 1989 |
| Decision date | Nov 17, 1989 |
| Days to decision | 213 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Cook Urological, Inc. |
| Location | Spencer, IN, US |
| Contact | MICHELLE YOUNG |
| 510(k) history | 104 submissions · 102 cleared · 1986-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k892855/>; Data sourced from FDA 510(k) public records (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. - Generated June 19, 2026