

K951106 SILICONE FOLEY CATHETERMay 25, 1995
76 days to decisionK951106 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k951106/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Mar 10, 1995
Decision date	May 25, 1995
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k951106/> 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