

K091767 3 WAY SILICONE FOLEY BALLOON CATHETEROct 9, 2009
114 days to decisionK091767 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k091767/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jun 17, 2009
Decision date	Oct 9, 2009
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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