

K053429 ADVANCED UROLOGICAL CATHETERFeb 8, 2006
61 days to decisionK053429 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k053429/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Dec 9, 2005
Decision date	Feb 8, 2006
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Entracare, LLC
Location	Irvine, CA, US
Contact	AL BOEDEKER
510(k) history	3 submissions · 3 cleared · 2004-2009

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