

**K190060 Urethrotech UCD**Oct 4, 2019  
266 days to decisionK190060 · Product code: **EZL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k190060/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jan 11, 2019
Decision date	Oct 4, 2019
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Urethrotech</b>
Location	Kingston Upon Thames, GB
Contact	Daniela Andrich
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Smith Associates</b>
Contact	Yolanda Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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