FDA 510(k) Premarket Notification

K190060 Urethrotech UCD

CLEARED

Oct 4, 2019
266 days to decision

K190060 · Product code: **EZL** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k190060/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Smith Associates**
Contact	Yolanda Smith

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