

K180354 UroGen Ureteral CatheterOct 30, 2018
264 days to decisionK180354 · Product code: **KOD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k180354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	Feb 8, 2018
Decision date	Oct 30, 2018
Days to decision	264 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Urogen Pharma, Ltd.
Location	Ra?Anana, IL
Contact	James G. Ottinger
510(k) history	5 submissions · 5 cleared · 2018-2021

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