

K211032 Urinary Catheter 12 Fr, Urinary Catheter 16 FrNov 19, 2021
226 days to decisionK211032 · Product code: **KOD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k211032/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	Apr 7, 2021
Decision date	Nov 19, 2021
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Urogen Pharma, Inc.
Contact	James G. Otinger

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

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