

K203321 Cystoject Syringe LeverDec 9, 2020
27 days to decisionK203321 · Product code: **QBL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k203321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Piston Syringe Lever (QBL)
Date received	Nov 12, 2020
Decision date	Dec 9, 2020
Days to decision	27 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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