

K190377 UroLift System UL400Mar 21, 2019
30 days to decisionK190377 · Product code: **PEW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k190377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implantable Transprostatic Tissue Retractor System (PEW)
Date received	Feb 19, 2019
Decision date	Mar 21, 2019
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Neotract, Inc.
Location	Pleasanton, CA, US
Contact	Brian Gall
510(k) history	17 submissions · 16 cleared · 2006-2023

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