

K201837 UroLift 2 System (formerly UL500), UroLift 2 Delivery Handle, UroLift 2 Implant CartridgeJul 31, 2020
29 days to decisionK201837 · Product code: **PEW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k201837/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implantable Transprostatic Tissue Retractor System (PEW)
Date received	Jul 2, 2020
Decision date	Jul 31, 2020
Days to decision	29 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201837/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026