

K153584 NeoTract UroLift System UL500Mar 15, 2016
91 days to decisionK153584 · Product code: **PEW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k153584/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Implantable Transprostatic Tissue Retractor System (PEW) |
| Date received | Dec 15, 2015 |
| Decision date | Mar 15, 2016 |
| Days to decision | 91 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Neotract, Inc. |
| Location | Pleasanton, CA, US |
| Contact | Nancy E Isaac |
| 510(k) history | 17 submissions · 16 cleared · 2006-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153584/> 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