FDA 510(k) Premarket Notification

K172359 UroLift System (UL500)

CLEARED

Aug 18, 2017
14 days to decision

K172359 · Product code: **PEW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k172359/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Implantable Transprostatic Tissue Retractor System (PEW)
Date received	Aug 4, 2017
Decision date	Aug 18, 2017
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neotract, Inc.**
Location	Pleasanton, CA, US
Contact	Louis-Pierre Marcoux
510(k) history	17 submissions · 16 cleared · 2006-2023