FDA 510(k) Premarket Notification

K222468 ArcTO Transobturator Sling System

CLEARED

Sep 15, 2022
30 days to decision

K222468 · Product code: **OTN** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k222468/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Aug 16, 2022
Decision date	Sep 15, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Urocure, LLC**
Location	Minneapolis, MN, US
Contact	John Nealon
510(k) history	3 submissions · 3 cleared · 2019-2022

REGULATORY CONSULTANT

Consulting firm	**Libramedical, Inc.**
Contact	Denise Lenz

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k222468/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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