

K222293 ArcSP Suprapubic Sling SystemSep 21, 2022
51 days to decisionK222293 · Product code: **OTN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k222293/>**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 1, 2022
Decision date	Sep 21, 2022
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Libra Medial, Inc.
Contact	Denise Lenz

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

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