

K183134 ArcTV Transvaginal Sling SystemFeb 7, 2019
86 days to decisionK183134 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k183134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator (OTN)
Date received	Nov 13, 2018
Decision date	Feb 7, 2019
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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