

K012628 GYNECARE TENSION-FREE VAGINAL TAPE SYSTEMOct 26, 2001
74 days to decisionK012628 · Product code: **OTN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k012628/>**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	Aug 13, 2001
Decision date	Oct 26, 2001
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gynecare Center
Location	Somerville, NJ, US
Contact	GREGORY JONES
510(k) history	1 submissions · 1 cleared · 2001-2001

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