

K033568 GYNECARE TVT OBTURATOR SYSTEMDec 8, 2003
26 days to decisionK033568 · Product code: **OTN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k033568/>**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	Nov 12, 2003
Decision date	Dec 8, 2003
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ethicon, Inc.
Location	Raritan, NJ, US
Contact	SEAN O'&BRYAN
Website	https://www.jnjmedtech.com
510(k) history	204 submissions · 197 cleared · 1976-2026

Ethicon, Inc. is a subsidiary of Johnson & Johnson specializing in surgical sutures and wound closure devices. The company is headquartered in Raritan, United States. Ethicon has received FDA 510(k) clearances from total submissions since 1976. The company's regulatory focus centers on General & Plastic Surgery devices, which represent the majority of its cleared submissions. The latest FDA 510(k) clearance was granted in 2026, demonstrating continued regulatory activity. Ethicon has manufactured surgical sutures and wound closure technologies since 1887. The company hold...