

K181151 GYNECARE TVT Abbrevo Continenence SystemAug 10, 2018
101 days to decisionK181151 · Product code: **PWJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181151/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrumentation, Surgical Mesh, Urogynecologic, Stress Urinary Incontinence (PWJ)
Date received	May 1, 2018
Decision date	Aug 10, 2018
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary
Other names	GYNECARE TVT Obturator Continenence System

APPLICANT

Company	Ethicon, Inc.
Location	Raritan, NJ, US
Contact	Debbie Fazen
Website	https://www.jnjmedtech.com
510(k) history	203 submissions · 196 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...
