

K173019 GYNECARE TVT Reusable Introducer, GYNECARE TVT Reusable Rigid Catheter Guide, GYNECARE TVT EXACT Continence System TrocarJul 6, 2018
281 days to decisionK173019 · Product code: **PWJ** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k173019/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrumentation, Surgical Mesh, Urogynecologic, Stress Urinary Incontinence (PWJ)
Date received	Sep 28, 2017
Decision date	Jul 6, 2018
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ethicon, Inc.
Location	Raritan, NJ, US
Contact	Melina Escobar
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...