

K201686 GYNECARE TVT™ System, GYNECARE TVT™ with Abdominal Guides System, GYNECARE TVT™ Introducer and Catheter Guide, GYNECARE TVT EXACT™ Continenence System and Trocar, GYNECARE TVT™ Obturator System and Passers and Winged Guide, GYNECARE TVT ABBREVO™ Continenence System and Passers and Winged Guide

Sep 17, 2020
87 days to decision

K201686 · Product code: OTN · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k201686/>

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	Jun 22, 2020
Decision date	Sep 17, 2020
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ethicon, Inc.
Location	Raritan, NJ, US
Contact	Ariell Joiner
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...