

K052401 GYNECARE TVT SECUR SYSTEMNov 28, 2005
88 days to decisionK052401 · Product code: **PAH** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k052401/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Female, Mini-sling (PAH) |
| Date received | Sep 1, 2005 |
| Decision date | Nov 28, 2005 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ethicon, Inc. |
| Location | Raritan, NJ, US |
| Contact | PATRICIA M HOJNOSKI |
| 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...