

K042603 GYNECARE PROLENE FASTENER SYSTEMDec 22, 2004
89 days to decisionK042603 · Product code: **PBQ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k042603/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fixation, Non-absorbable Or Absorbable, For Pelvic Use (PBQ)
Date received	Sep 24, 2004
Decision date	Dec 22, 2004
Days to decision	89 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...
