

**K013718 GYNEMESH PROLENE SOFT (POLYPROPYLENE)
NONABSORBABLE SYNTHETIC SURGICAL MESH FOR PELVIC
FLOOR REPAIR**Jan 8, 2002
61 days to decisionK013718 · Product code: **OTO** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k013718/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Synthetic, Urogynecologic, For Apical Vaginal And Uterine Prolapse, Transabdominally Placed (OTO)
Date received	Nov 8, 2001
Decision date	Jan 8, 2002
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gynecare, A Div. of Ethicon, Inc.
Location	Somerville, NJ, US
Contact	GREGORY R JONES
510(k) history	2 submissions · 2 cleared · 2002-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013718/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026