FDA 510(k) Premarket Notification

CLEARED

K180829 PROLENE Polypropylene Mesh Non-Absorbable Synthetic Surgical Mesh, PROLENE (Polypropylene) Hernia System, Non-absorbable Synthetic Surgical Mesh

Jun 28, 2018
90 days to decision

K180829 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k180829/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Mar 30, 2018
Decision date	Jun 28, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ethicon, Inc.**
Location	Raritan, NJ, US
Contact	Stephanie Saati
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...