CLEARED

K984220 MODIFICATION OF PROLENE (POLYPROPYLENE) HERNIA SYSTEM, NONABSORBABLE SYNTHETIC SURGICAL MESH

Feb 23, 1999
90 days to decision

K984220 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k984220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Nov 25, 1998
Decision date	Feb 23, 1999
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ethicon, Inc.**
Location	Raritan, NJ, US
Contact	GREGORY R JONES
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...