

**K181268 PROLENE (Polypropylene) 3D Patch**Jul 26, 2018  
73 days to decisionK181268 · Product code: **FTL** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k181268/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	May 14, 2018
Decision date	Jul 26, 2018
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ethicon, Inc.</b>
Location	Raritan, NJ, US
Contact	Melina Escobar
Website	<a href="https://www.jnjmedtech.com">https://www.jnjmedtech.com</a>
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...

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