

**K252743 STRATAFIX™ Spiral PDS™ Plus Knotless Tissue Control Device**Dec 22, 2025  
116 days to decisionK252743 · Product code: **GAM** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k252743/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Aug 28, 2025
Decision date	Dec 22, 2025
Days to decision	116 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary
Other names	STRATAFIX™ Spiral MONOCRYL™ Plus Knotless Tissue Control Device

**APPLICANT**

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Company	<b>Ethicon, Inc.</b>
Location	Raritan, NJ, US
Contact	Samantha Mecker
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...