

# K151200 STRATAFIX Spiral MONOCRYL Knotless Tissue Control Device, STRATAFIX Spiral MONOCRYL Plus Knotless Tissue Control Device

Aug 13, 2015  
100 days to decision

K151200 · Product code: **GAM** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k151200/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	May 5, 2015
Decision date	Aug 13, 2015
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Ethicon, Inc.</b>
Location	Raritan, NJ, US
Contact	DONNA MARSHALL
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...