

**K221744 STRATAFIX™ Spiral MONOCRYL™ Plus Knotless
Tissue Control Device**Nov 15, 2022
152 days to decisionK221744 · Product code: **GAM** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221744/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Jun 16, 2022
Decision date	Nov 15, 2022
Days to decision	152 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ethicon, Inc.
Location	Raritan, NJ, US
Contact	Jenny Wang
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...