FDA 510(k) Premarket Notification

CLEARED

K192580 STRATAFIX Spiral Monocryl, Plus Bidirectional Knotless Tissue Control Device

Dec 18, 2019
90 days to decision

K192580 · Product code: **GAM** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k192580/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Absorbable, Synthetic, Polyglycolic Acid (GAM)
Date received	Sep 19, 2019
Decision date	Dec 18, 2019
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ethicon, Inc.**
Location	Raritan, NJ, US
Contact	Eleanor Zhou
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...