

K192144 STRATAFIX Spiral PDS Plus Bidirectional Knotless Tissue Control DeviceMar 25, 2020
230 days to decisionK192144 · Product code: **NEW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k192144/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Aug 8, 2019
Decision date	Mar 25, 2020
Days to decision	230 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...

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Device record: <https://www.510kdatabase.net/k192144/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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