

K182873 STRATAFIX Symmetric PDS Plus Knotless Tissue Control Devices, STRATAFIX Spiral PDS Plus Knotless Tissue Control Devices, STRATAFIX Spiral MONOCRYL Plus Knotless Tissue Control Devices, STRATAFIX Spiral MONOCRYL Knotless Tissue Control Devices

Jan 10, 2019
90 days to decision

K182873 · Product code: **NEW** · General & Plastic Surgery

Source: <https://www.510kdatabase.net/k182873/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Oct 12, 2018
Decision date	Jan 10, 2019
Days to decision	90 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ethicon, Inc.
Location	Raritan, NJ, US
Contact	Ariell Joiner
Website	https://www.jnjmedtech.com
510(k) history	204 submissions · 197 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/k182873/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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