

K261988 Monodek™ (POLYDIOXANONE) Dyed Violet
Monofilament Synthetic Absorbable Surgical Suture

Jul 9, 2026
27 days to decision

K261988 · Product code: NEW · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k261988/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Jun 12, 2026
Decision date	Jul 9, 2026
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teleflex Medical, LLC
Location	Morrisville, NC, US
Contact	Laura Medlin
510(k) history	2 submissions · 2 cleared · 2026-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k261988/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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