

**K192490 Tevdek II, Silky II Polydek, &apos;Cottony&apos; II, NextStitch**Mar 30, 2020  
201 days to decisionK192490 · Product code: **GAT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192490/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Sep 11, 2019
Decision date	Mar 30, 2020
Days to decision	201 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Teleflex Medical</b>
Location	Fall River, MA, US
Contact	Robin Haden
510(k) history	39 submissions · 39 cleared · 2003-2025

Teleflex Medical is an American medical device company headquartered in Wayne, Pennsylvania, with operations in Fall River, US. The company is a major provider of specialty medical devices for critical care and surgical procedures. Teleflex Medical has received FDA 510(k) clearances from total submissions since 2003. The company maintains active regulatory engagement, with the latest clearance in 2025. Its cleared devices span multiple specialties including anesthesiology, general and plastic surgery, cardiovascular, and vascular access systems. The company&apos;s product port...

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