

K193530 Deklene MAXXMar 19, 2020
90 days to decisionK193530 · Product code: **GAW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193530/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Nonabsorbable, Synthetic, Polypropylene (GAW)
Date received	Dec 20, 2019
Decision date	Mar 19, 2020
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Teleflex Medical
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's product port...