

K153076 silky II POLYDEK, cottony II, TEVDEK II, NextStitch, DEKLENE II, DEKLENE MAXX Gabbay-Frater, NYLON, SILK, STAINLESS STEELJun 16, 2016
237 days to decisionK153076 · Product code: **GAT** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k153076/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Oct 23, 2015
Decision date	Jun 16, 2016
Days to decision	237 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Teleflexmedical, Inc.
Location	Jeffrey, NH, US
Contact	Natalie Hichak
510(k) history	64 submissions · 61 cleared · 1985-2024

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