

K063194 TUFFLEX POLYESTER SUTUREDec 4, 2006
45 days to decisionK063194 · Product code: **GAT** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k063194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Oct 20, 2006
Decision date	Dec 4, 2006
Days to decision	45 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Axya Medical, Inc.
Location	Beverly, MA, US
Contact	HOWARD L SCHRAYER
510(k) history	19 submissions · 19 cleared · 1998-2007

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