

K970416 ACUFEX DOUBLE ARMED SUTURE NEEDLEApr 21, 1997
76 days to decisionK970416 · Product code: **GAT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k970416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Feb 4, 1997
Decision date	Apr 21, 1997
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew Endoscopy, Inc.
Location	Andover, MA, US
Contact	SUSAN A FINNERAN
510(k) history	18 submissions · 17 cleared · 1996-2011

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