

K981128 SOFSILK SUTUREMay 11, 1998
42 days to decisionK981128 · Product code: **GAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k981128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Silk (GAP)
Date received	Mar 30, 1998
Decision date	May 11, 1998
Days to decision	42 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	United States Surgical, A Division of Tyco Healthc
Location	Mchenry, IL, US
Contact	JAMIE YIEH
510(k) history	218 submissions · 200 cleared · 1977-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981128/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 20, 2026