

K261484 Tissue Approximation SystemJun 3, 2026
29 days to decisionK261484 · Product code: **GAR** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k261484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Nonabsorbable, Synthetic, Polyamide (GAR)
Date received	May 5, 2026
Decision date	Jun 3, 2026
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Tas Medical, Inc.
Location	San Carlos, CA, US
Contact	Thomas Kramer
510(k) history	2 submissions · 2 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	Oconnell Regulatory Consultants, Inc.
Contact	Maureen OConnell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k261484/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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