

K250977 Suture-TOOL SystemApr 28, 2025
28 days to decisionK250977 · Product code: **NEW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250977/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Suture, Surgical, Absorbable, Polydioxanone (NEW)
Date received	Mar 31, 2025
Decision date	Apr 28, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suturion AB
Location	Lund, SE
Contact	Paan Hermansson
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Target Health
Contact	Adam Harris

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250977/> 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 14, 2026