

**K221767 Surgical Sutures with or without Needle**Jul 31, 2023  
409 days to decisionK221767 · Product code: **GAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221767/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Silk (GAP)
Date received	Jun 17, 2022
Decision date	Jul 31, 2023
Days to decision	409 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Huaian Seamen Medical Technology Co., Ltd.</b>
Location	Huaian, CN
Contact	Xinjie Zhang
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Tianjin Zongxin Weiye Consulting Co, Ltd.</b>
Contact	Liu Hui

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221767/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026