

K260197 Shogun Axis™ Fascial Closure System (1018S, 1018B, 1218S, 1218B, 1518S, 1518B)Apr 8, 2026
76 days to decisionK260197 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k260197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jan 22, 2026
Decision date	Apr 8, 2026
Days to decision	76 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Shenyun Medical Equipment Co., Ltd.
Location	Suzhou, CN
Contact	Yuan Liu
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Zhihe Info-Tech(Suzhou) Co., Ltd.
Contact	Rachel Yu

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/k260197/>; 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 13, 2026