

K250551 4K Endoscopic Camera System (SV-800, SV-800I, SV-800R, SV-800N)Oct 2, 2025
219 days to decisionK250551 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k250551/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Feb 25, 2025
Decision date	Oct 2, 2025
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Sophway Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Shuting Chen
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Eva Li

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/k250551/> 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