

**K250204 Endoscopic Camera System**Jul 1, 2025  
158 days to decisionK250204 · Product code: **FET** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k250204/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Video Imaging System/component, Gastroenterology-urology (FET)
Date received	Jan 24, 2025
Decision date	Jul 1, 2025
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Sophway Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Peter Ye
510(k) history	2 submissions · 2 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250204/> 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 13, 2026