

**K250917 Flexible Ureterorenoscope system (Electronic Endoscope Image Processor, model: SP-TXCLQ12.1, Flexible Ureterorenoscope, model: SP-SNGSYJ 2.0, SP-SNGSYJ 2.2, SP-SNGSYJ 2.5, SP-SNGSYJ 2.8)**Oct 31, 2025  
218 days to decisionK250917 · Product code: **FGB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k250917/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Mar 27, 2025
Decision date	Oct 31, 2025
Days to decision	218 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Sanping Image Technology Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Chen Salon
510(k) history	2 submissions · 2 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Imd Medical &amp; Drug Technology Service Institutions</b>
Contact	Chen Salon

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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