

**K211686 Flexible Video-Choledo-Cysto-Ureteroscope System**Feb 22, 2022  
265 days to decisionK211686 · Product code: **FGB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k211686/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Jun 2, 2021
Decision date	Feb 22, 2022
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shanghai SeeGen Photoelectric Technology Co., Ltd.</b>
Location	Shanghai, CN
Contact	Yvonne Fei
510(k) history	6 submissions · 6 cleared · 2022-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Vanhe Consulting Co., Ltd.</b>
Contact	Nick Wang

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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