

**K212458 Flexible Video-Uretero-Renoscope SSU System**Jan 20, 2022  
168 days to decisionK212458 · Product code: **FGB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k212458/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Aug 5, 2021
Decision date	Jan 20, 2022
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Karl Storz Endoscopy America</b>
Location	Los Angeles, CA, US
Contact	Mario Trujillo
510(k) history	5 submissions · 5 cleared · 2020-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212458/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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