

**K232911 KARL STORZ Flexible Uretero-Reno-Fiberscope FLEX-X2S [positive deflection] (11278A2), KARL STORZ Flexible Uretero-Reno-Fiberscope FLEX-X2S [contra-positive deflection] (11278AU1)**Jun 10, 2024  
265 days to decisionK232911 · Product code: **FGB** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k232911/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Sep 19, 2023
Decision date	Jun 10, 2024
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>Karl Storz Endovision, Inc.</b>
Location	Charlton, MA, US
Contact	Thomas Ostrowski
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Karl Storz Endoscopy America, Inc.</b>
Contact	Jennifer Downing

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232911/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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