

**K232837 Uro-G HD Flexible Cystoscope**Jun 7, 2024  
267 days to decisionK232837 · Product code: **FAJ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k232837/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Sep 14, 2023
Decision date	Jun 7, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Uroviu Corporation</b>
Location	Bellevue, WA, US
Contact	Thom Lawson
510(k) history	7 submissions · 7 cleared · 2018-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232837/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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