

**K243196 Uro-G HD Cystoscope (1520)**Dec 13, 2024  
73 days to decisionK243196 · Product code: **FAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k243196/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Oct 1, 2024
Decision date	Dec 13, 2024
Days to decision	73 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	Thomas 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/k243196/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026