

**K250797 UV5000 Handle**Sep 11, 2025  
181 days to decisionK250797 · Product code: **FAJ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k250797/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Mar 14, 2025
Decision date	Sep 11, 2025
Days to decision	181 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/k250797/> 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