

K253226 UV5000W HandleOct 23, 2025
24 days to decisionK253226 · Product code: **FAJ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k253226/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Sep 29, 2025
Decision date	Oct 23, 2025
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Uroviu Corporation
Location	Bellevue, WA, US
Contact	Thomas Lawson
510(k) history	7 submissions · 7 cleared · 2018-2025

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