

**K212202 WiScope Digital Cystoscope System, WiScope Single-Use Digital Flexible Cystoscope, WiScope Image System**Apr 13, 2022  
273 days to decisionK212202 · Product code: FAJ · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k212202/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cystoscope And Accessories, Flexible/rigid (FAJ)
Date received	Jul 14, 2021
Decision date	Apr 13, 2022
Days to decision	273 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>OTU Medical, Inc.</b>
Location	San Jose, CA, US
Contact	Geping Liu
510(k) history	5 submissions · 5 cleared · 2018-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Zi-medical, Inc.</b>
Contact	Mingzi Hussey

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

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