

K210579 WiScope OM Endoscope System, WiScope Single-Use Digital Flexible Ureteroscope.Choledochoscope, WiScope Image SystemJul 22, 2021
146 days to decisionK210579 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k210579/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ureteroscope And Accessories, Flexible/rigid (FGB)
Date received	Feb 26, 2021
Decision date	Jul 22, 2021
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Zi-medical, Inc.
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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