

K220399 WiScope Digital Bronchoscope System, WiScope Single-Use Digital Flexible Bronchoscope, WiScope Image SystemJun 16, 2022
125 days to decisionK220399 · Product code: **EOQ** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k220399/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Feb 11, 2022
Decision date	Jun 16, 2022
Days to decision	125 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
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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