

K181977 WiScope Digital Endoscope SystemAug 14, 2018
21 days to decisionK181977 · Product code: **FGB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181977/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ureteroscope And Accessories, Flexible/rigid (FGB) |
| Date received | Jul 24, 2018 |
| Decision date | Aug 14, 2018 |
| Days to decision | 21 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181977/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026