

K183433 FUJIFILM Ultrasonic EndoscopeSep 5, 2019
268 days to decisionK183433 · Product code: **ODG** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k183433/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Ultrasound System, Gastroenterology-urology (ODG) |
| Date received | Dec 11, 2018 |
| Decision date | Sep 5, 2019 |
| Days to decision | 268 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Fujifilm Corporation |
| Location | Ashigara Kami-Gun, JP |
| Contact | Randy Vader |
| 510(k) history | 63 submissions · 63 cleared · 2018-2026 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Fujifilm Medical Systems U.S.A, Inc. |
| Contact | Jeffrey Wan |

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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