

**K182051 FUJIFILM Duodenoscope Model**Oct 2, 2018  
63 days to decisionK182051 · Product code: **FDT** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k182051/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Duodenoscope And Accessories, Flexible/rigid (FDT)
Date received	Jul 31, 2018
Decision date	Oct 2, 2018
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Fujifilm Medical Systems U.S.A, Inc.</b>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182051/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026