

**K181763 FUJIFILM Ultrasonic Endoscope**Jul 27, 2018  
24 days to decisionK181763 · Product code: **FDS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k181763/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastroscope And Accessories, Flexible/rigid (FDS)
Date received	Jul 3, 2018
Decision date	Jul 27, 2018
Days to decision	24 days
Third-party review	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	62 submissions · 62 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181763/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 30, 2026